Five - Y ear 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 witl external ultrasonic device that facilitates the c10sed capsulotomy tech¬nique. A set of 52 patients have l treated with a 82.6% of improvement at ayear 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 unelea 7,13]. Although the implantation of rugous surface coat¬ing implants [4,8,10,15] and several adrninistra¬tions [1,2,5,6,12,17] have diminished the percentage of contracture, they still occur. Exte ultrasonic treat¬ment has proven to be effective on wound healing and it is used in disorders such as cellu keloidal scarring, selerodermia, Dupuitren's, Peyronie's diseases and joint alterations [9,16,18]. Five years we started applying external ultrasounds to treat breast contractures. Prelimi¬nary results were so satisfac that we were encour¬aged to continue [14].

In this study we investigate the results of ultrasound treatment of contractured breast implants. The princ statistical characteristics of the population under study are described in relation to their age and initial imp contracture grade. A total of 52 patients are analyzed, 25 of which have bilateral contractures; these pati 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 wit cor¬relation to implant contracture improvement, as assessed by its Baker grade. The principal investiga method used to analyze the effect of the treatment on the implant contracture grade is expressed throug change be¬tween initial and post-treatment assessments. In patients with bilateral contractures, a differe analysis is also conducted so as to establish whether the effects of the treatment are essentially of local or local nature.

Particular attention is paid to a subset of the popula¬tion under study which outperforms the full set. ex¬planation of its behavior is sought by comparing this subset, which is referred as subset A, to the ful 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-spe data and implant-specific data. Patient-specific data in¬eludes: an identifier, age, brand, surgical plane, num¬ber of ultrasound sessions, three parameters giving the contracture onset time (period following imp in which it formed), and its assessment time (period in which the patient had a formed contracture be com¬ing in for treatment). Implant-specific data ineludes the side of the patients on which the spe prosthesis is placed, its volume, and the contracture grade at the initial assessment, post-treatment, and fol up.

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

lnitial assessment grade. The distribution of the initial assessment grade for the full set of contractured impl is shown in Fig. 1. Only 19% of the implants have a contracture grade of IV on the Baker scale, while the remaining 81 % are distributed in the III and 11 Baker scale grades. In fact, almost half of the implants hav initial Baker grade of III.

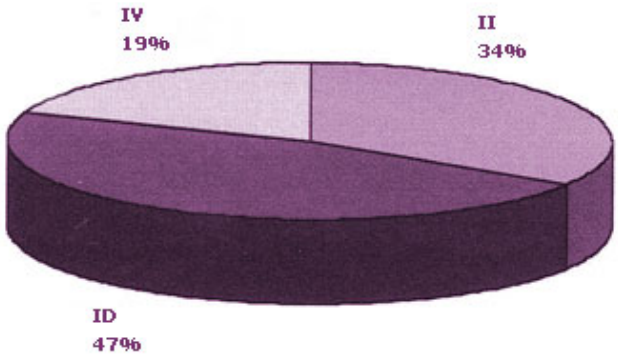

Fig. 1. Distribution of initial assessment grade.

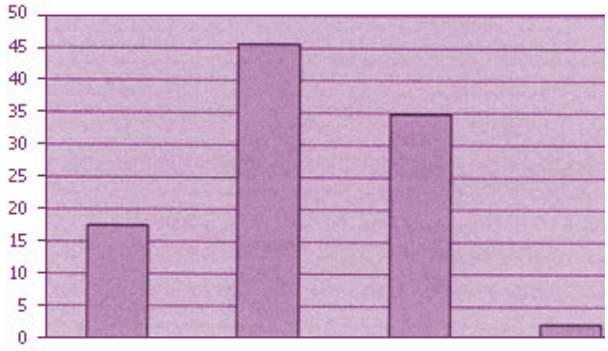

Fig. 2. Distribution of long-term progress (L

Bilateral implants. Patients having bilaterally contrac¬tured implants represent 48% of the cases, but contri to 65% of the contractures, and so require special atten¬tion when effects of non-local nature may important. The results indicates that the vast majority of patients have similar contractures on both breasts. may in¬dicate that what determines the initial contracture degree in a patient is non-local in nature.

Analysis of the Effects of the Treatment

Analysis 01 the Ultrasonic Sessions

The number of sessions is determined during treatment by evaluating the actual improvement. Patients treated by repeated ultrasonic applications, ranging from 2 to 16 sessions. The average number of sessio 6.4.
The experimental protocol followed during the ultra¬sonic treatment may be the key in explaining distri¬bution obtained; requests on the part of the patients for both terminating prematurely or extending number of applied ultrasonic sessions, are followed. This indicates that patient satisfaction is an impo element of this study. In the paragraph dedicated to the correlation of change with number of ultrasc sessions, a further breakdown of this data may be found.

Comparison 01 Change Between lnitial and Post-treatment Assessments

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

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

Long-term progress. The data available for the analysis of the long-term effects of the treatment does encom¬pass the full statistical population, as only a subset of patients were interviewed long after treatment. In fact, these implants represent 65% of those in the study, so that a substantial variation with res to the full population may be expected. This important aspect is investigated in the section dedicated to analysis of subset A.

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Short-term progress. The analysis of the short-term progress, which is represented in Fig. 3, is based o implants, and indicates that an improvement, given by a change of greater than O in the Baker assess 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 ca analyzed so that the overall behavior of the patient population can be described. In Fig. 4, the distributic the contrac¬tures at this stage is shown, while in Table 1 the percent¬ages of this distribution are compare those prior to treatment and at long termo In absolute term, almost half of the implants achieve the possible post-treatment assessment grade. For subset A, the results are even bet¬ter (Tables 2, 3). Tables 2 3 compare the results 'of the full set (2) to those of subset A (3). The number of implants which obtair assessment grade is listed in the row, and the number which had an assessment prior to treatment is listed i column

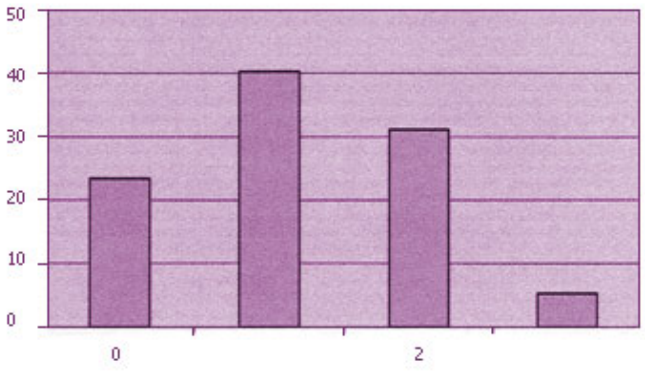

Fig. 3. Distribution of short-tenn progress (STP).

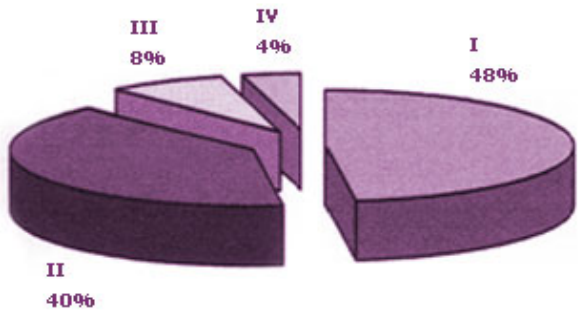

Fig. 4. Distribution of contractures after treatn

Distribution

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

Table 1. Distribution of contractures post-treatmer

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

Table 2. Full-set post-treatment assessments.

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

Table 3. Subset A post-treatment assessments

Bilateral Contractures

Limiting this short-term analysis to cases with bilateral contractured implants, a comparison of the evolutic the two contractures on the sarne patient can be made. Specifically, the difference in improvement betwee two implants is shown indicating that 28% of the bilat¬eral contractures improves in to a different degree. possible explanation for this slight asymmetric behavior, is that the effect of the treatment is of local na

This effect is also portrayed in the comparison of bilateral asymmetries in pre-treatment and in post-treatı as¬sessments where, for differences greater than one, the post-treatment implants have a greater presence.

Relationship of change to number of ultrasound ses¬sions. The question of how many ultrasound sessions optimal from a treatment point of view is important. In order to identify the relationship between the numb sessions a patient receives and the effect that they pro¬duce, it is necessary to recall that the experim pro¬tocol inc1udes the patient satisfaction factor which is a subjective evaluation of the effective change. inter¬esting to note that the 4 cases with the maximum amount of change (3) are obtained with just 5 sessi There seems to be no evidence suggesting that more sessions result in a greater effect. In fact, with fewer 8 ses¬sions we obtain a satisfactory result on 75% of contrac¬tures.

Relationship of short-term progress to surgical planeo The breakdown of the data regarding surgical plane function of short-term progress is the basis of the analysis of the correlation between these two vari¬ables we can see in Table 4 the mean for short-term progress related to cases with a pre-pectoral surgical pla greater than the mean related to cases with a retro-pectoral surgical plane (Table 4). In Fig. 5 the nor¬mal 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 per to a portion of these who were interviewed a substantial period after the application of the ultras treatment. This group of patients shall be referred to as subset A. Some of subset A's properties are g special attention in this analysis.

lntroduction of subset A group. The population of subset A is composed of 34 patients, 14 of whom bilateral contractures, for a total of 48 implants. Therefore, the 59% of patients inc1uded in the subset that unilat¬eral contractures only make up 42% ofthe subset's total number of implants. This is similar to the set popu¬lation 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 t two sets are compatible. The probability associated to the chi-squared statistic comparing these two data se 92%, so it is reasonable to as sume that there was no substantial difference in the distribution of their in assessment grade.

STP	SurgicaI plane		
	PP	RP	Post mastectomy
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-tenn progress.
PP: pre-pectoral.
RP: retro-pectoral

Table 4. SurgicaI plane and short-tenn progress.

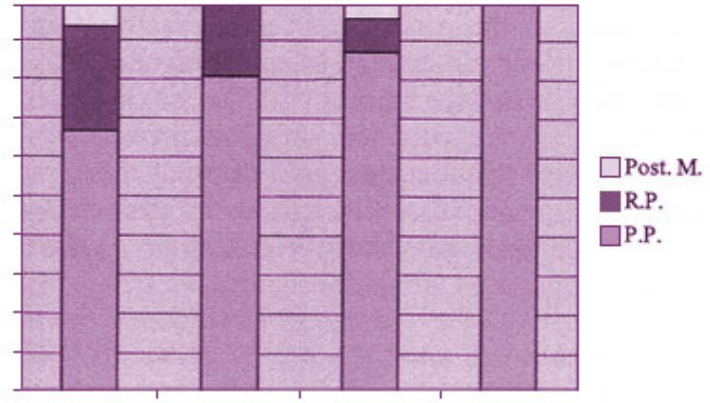

Fig. 5. Nonnalized breakdown of surgical plane versus

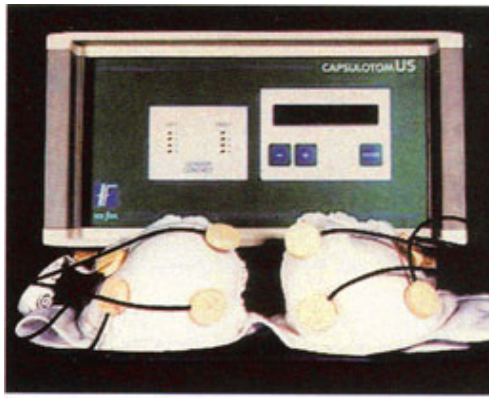

Fig. 6. ExternaI ultrasonic de

short¬term progress. Abbreviations used: STP, short-term progress; Post. M., postmastectomy; R.P., retro-pectoral; P.P., pre¬pectoral.

Short-term progress in subset A. Differences made evi¬dent comparing long-term progress to short- prog¬ress are significant, so a specific analysis was used to determine the cause of this disagreement previously indicated, no significant differences in the initial assess¬ment distribution are found in the ful population as compared to subset A. However, the short-term progress made by these to groups differs slig when analyzed using the short-term change statistics and the post¬treatment assessment statistics of these groups

Regarding short-term change, the probability associ¬ated 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 set group has a noticeably greater number of cases with no short-term change. However, the post-treatment as¬sessment results do not conc1usively 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%.

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

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

Materials and Methods

The ultrasonic device we used in our treatments is simi¬lar to the one applied for superficial soft-ti treatment. A 2 MHz generator permits us to reach deep layers of fibrotic tissue. The device is connected transducers, 4 on each breast, oriented towards the capsule, with ad¬justable power per outlet, varying fro to 15 W to produce a maximum power density of 3 W/cm2 (Fig. 6). The setting used was 15 W with a po per transductor of 500 W!cm2. The device could be set in continuous or pul sed emission. In any case once values of power emission per outlet and of total produced energy have been set, the appliance automati calculated the cyc1e duration needed to distribute that energy to the transduc¬ers. We used the pul sed emis since the cyc1e is up to five times longer in that position, to minimize the over¬heating effect of ultras energy on tissues. The ses¬sions were scheduled every 24 h, until a good and stable result was obtained. 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 nitrofurazone leaving no saequela. We recornmend applying enough gel to the transductors to avoid this of complication.

Discussion

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

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

In a preceding study of 24 patients, not inc1uded in this work [14], but treated equally to this set, we found 82% of cases resulted in Baker I state, and in 97% of cases the contracture improved by at least one B degree. Joining both studies, we found that 58.6% of contractures improved to Baker 1, and 83.8% improv least one degree at the year follow-up.

The terminal effect of the ultrasonic energy increases the speed of cellular metabolism and stimu fibro¬blast activation and wound healing [9, 16]. In continuous emission the termical effect can produce b and pro¬tein denaturation. To avoid these complications we have applied pulsed emission. The effects o external ul¬trasonic administrations are maximized at the interface between two layers of tissues with diffe characteris¬tics of acoustic impedimento The contracted fibrous cap¬sule and the marnmary implant su are a acoustic interface. Lesesne [10] demonstrated that there is a high rate of silicone droplets enc10sed i

are a acoustic interface. Lesesne [10] demonstrated that there is a high rate of silicone droplets enclosed i capsular tissues. In OUT opinion, all these events can contribute to change the implant capsular struc improving tissue metabo¬lism and preventing its fibrotic contracture.

Conclusions

Results obtained in this work (83.8% improvement at a year follow-up) can conf111Il the evidence of caps softening and easier c10sed capsulotomy after external ultrasonic treatrnent. In most cases a limited numb sessions, fewer than 8, are enough to obtain a long-term result. We also can confirm that cases in whicl im¬plant was placed in the pre-pectoral plane, the percentage of improvement was higher. Furtherm external ultra¬sonic treatrnent has proved easy to apply, well-accepted by the patient, cost-effective, and fr significant com¬plications. We are currently evaluating this therapy's po¬tential in the prevention of caps contracture, the re¬sults of which we will publish in the future.

References

1. Berman B, Duncan MR: Pentoxifyline inhibits normal hu¬man dermal fibroblast in vitro prolifera collagen, gly¬cosaminglycans, and fibronectin production, and increases collagenase activity. J ln DermatoI92:605, 1989
2. Berman B, Duncan MR: Pentoxifyline inhibits the prolif¬eration of human fibroblasts derived from ke sclero¬derma, and morphea skin, and their production of collagen, glycosaminglycans and fibronectin. E Dermatol 123:339, 1990 .
3. Burkhardt BR: Capsular contracture: hard breasts, soft data. Clin Plast Surg 15:521, 1988
4. Burkhardt BR, Eades E: The effect of Biocell texturing and povidone-iodine irrigation on caps contracture around saline-inflatable breast implants. Plast Reconstr Surg 96: 1317, 1995
5. Caffee HH, Rotatori DS: Intracapsular injection of triam¬cinolone for prevention of the contracture. l Reconstr Surg 92:1073, 1993
6. Ellemberg AH: MarkOO thinning of breast skin flaps after the insertion of implants contai triamcinolone. Plast Reconstr Surg 60:755, 1977
7. Georgiade NG: Aesthetic surgery of the breast. WB Saunders Co.: Philadelphia, 1990
8. Handel N, Jensen A, Black Q: The fate of breast implants: a critical analysis of complications and outco Plast Reconstr Surg 96:1521, 1995
9. Lehmann JF, De Lauter BJ: Diatermia y terapeutica super¬ficial con calor, laser y frio. In: Krusen J Medicina fisica y rehabilitation, 4th oo. Editorial Medica Panameri¬cana: Madrid, 1994
10. Lesesne CB: Textured-surface silicone breast implants: histology in the humano Aesth Plast Surg 2 1997
11. Little G, Baker JL: Results of closOO compression capsu 10tomy for treatment of contracted breast imp capsules Plast Reconstr Surg 65:30, 1980
12.Marin Bertolin S: ProfIlaxis de la contractura capsular me diante pentoxifilina intraprotesica: est experimental en ratas. Cir Plast lberolatinoamer 23(4):373, 1997
13. McCarthy JG: Plastic Surgery, Vol. VI. WB Saunders Co.: Philadelphia, 1990
14. Planas J, et al.: External ultrasonic treatment of capsula contractures in breast implants. Aesth Plast 21:395, 1997
15. Rioja Torrejón L, et al.: Estudio comparativo de las com¬plicaciones de los implantes texturados rell de gel de silicona en oposición a los de relleno de suero. Cir Plast lbero-latinoameric 24(4):, 1998
16. Scott WW, Scardino PL: A new concept in the treatment of Peyronie's disease. South Med J 41:173, 19
17. Spear SL, Matsuba H, Rornm S, Little JW: Methyl prOO¬nisolone in double-lumen gel-saline submus mam¬mary prostheses: a double-blind prospective, controlled clinical trial. Plast Reconstr Surg 87: 1991
18. Williarns AR, Chater BV, Allen KA, Sanderson JH: The use of P tromboglobulin to detect platelet dan by thera¬peutic ultrasound in vivo. J Clin Ultrasound 9:145, 1981