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Preliminary Study of Non-invasive Shock Wave Treatment of Capsular Contracture after Breast Implant: Animal Model

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Abstract— **The incidence rate of capsular contracture after breast implant is about 8% to 12%. Patients would feel extremely uncomfortable after scar formation. Administering oral medications (such as vitamin E and Zafirlukast tablets, etc.) or invasive breast capsulectomy surgery was commonly used for capsular contracture repair in clinical therapy. However, the therapeutic effect is still under investigation. Shock waves can be used to remove soft connective tissue in clinical applications. It has been widely used in orthopedics and rehabilitation. No related research paper about shock wave treatment of capsular contracture has been published yet. It might provide another choice for capsular contracture repair. In order to simulate breast implantation, two silica-gel bags filled with normal saline were implanted into New Zealand rabbit's thighs bilaterally as an animal model. Six weeks later, daily shock wave treatment on the right thigh was performed for six weeks after capsular contractures were formed, while the other thigh was used as a control. Then, magnetic resonance imaging (MRI) was used to compare the difference between treated and un-treated thighs. Afterwards, pathological sections were analyzed to confirm the findings. It has been demonstrated that shock wave treatments are capable of changing the structure and composition of capsular contractures. The structure of scar became** myxoid **changed or collagen deposition of scar decreased after shock wave treatment, hence, the formation of scars decreased. Increased myxoid and decreased collagen deposition has also been found.**

Key words: Capsular contracture, Shock wave, Breast implant, Magnetic resonance imaging.

I. Introduction

Breast implant surgery has been widely used as an important therapeutical option for breast augmentation, breast cosmetology and breast reconstruction after oncoplastic surgery.[1-3] The most common and important complication is capsular contracture after breast implant surgery. The incidence rate of capsular contracture after breast implant has been reported to be about 8% to 12%. Furthermore, a 20% to 40% incidence rate has also been reported.[1-2,4] Patients would feel extremely uncomfortable and painful after scar formation which might result in the burden of frontal breast. Several common ways to alleviate this complication in clinical treatment are listed as follows:

1. Invasive surgery (such as breast capsulectomy)[3,5-6]
2. Use of implant materials with rough surface[7-8]
3. Massage after surgery[9-10]
4. Use of antibiotics after breast implant [11-12]
5. Use of therapeutical oral medications (vitamin E and Zafirlukast tablets, etc.)[11-12]
6. Breast implant removal surgery

Recently, shock waves have been widely used to get rid of soft connective tissue in clinical applications including orthopedics and rehabilitation. Shock waves used to purge passé scar, ligament injury and joints injury has been demonstrated that it might be effective to remove scar tissue and stimulate tissue regeneration. It might provide another choice for capsular contracture repair. As far as we know, no related research paper about shock wave treatment of capsular contracture has been published. Neither has the animal model. The purpose of this study is to simulate scar formation of breast implant using an animal model and evaluate the feasibility and effectiveness of shock wave therapy. It is expected to provide an alternative treatment method to effectively relieve patients' pain for breast augmentation surgery after this innovative animal shock wave treatment study.[13-15]

II. Materials and Methods

The shock wave therapy equipment used was BTL-5000 SWT power (Ivermedi Ltd.). The animal use protocol of this study was reviewed and approved by the institutional animal care and use committee (IACUC) of I-Shou University. Four New Zealand rabbits were used in this experiment. A one centimeter cut was made on each thigh of New Zealand rabbit after anesthesia using Zoletil and Rompum. Then, two 25 ml silica-gel bags filled with normal saline were implanted between subcutaneous fatty tissue and the muscle layer of the New Zealand rabbit's thighs bilaterally as an animal model. This animal model has been demonstrated to be able to form capsular contractures successfully.[13-15] The right thigh was classified as the experimental group (shock wave treatment) and the left thigh was classified as the control group (non -shock wave-treatment). Capsular contractures were formed six weeks after implant, followed by performing daily shock wave treatment (1.5 bar, 1500 shots) on the implanted region of right thigh for six weeks. Then, magnetic resonance

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imaging (MRI) scans were performed and MR images were used to interpret and compare the difference between treatment and non-treatment thighs. Siemens MAGNETOM Skyra 3T clinical use whole body scanner was used in this study. The scanning pulse sequences were turbo spin echo Fat Saturation (TSE-FS) and susceptibility weighted imaging (SWI) pulse sequences. The scanning parameters for TSE FS were FOV = 180 mm, slice thickness = 6.5 mm, TR = 2200 ms, TE = 10 ms, BW = 149Hz/pixel, image matrix = 256 × 256 and NEX = 4, while the scanning parameters for SWI were FOV = 180 mm, slice thickness = 1.94 mm, TR = 27 ms, TE = 20 ms, flip angle = 15°, BW = 149Hz/pixel, image matrix = 256 × 256 and NEX = 1. Afterwards, pathological sections postmortem for both implanted regions were analyzed to verify the difference of scar thickness, scar structure and compositions between both groups and to confirm the MRI findings.

III. Results

One of the TSE-FS T2-weighted images (T2WI) after shock wave treatments is shown in figure 1. It shows that both the silica-gel bags and muscle layers have clear and smooth interfaces. Hyper-intensity signal was shown on the muscle of the thigh with treatment, which might be because muscle tissue became fluffy and the composition of capsular contracture changed. MR susceptibility-weighted minimum intensity projection image (SWI-mIP) after shock wave treatments is shown in figure 2. The surface of the muscle layer of the thigh with shock wave treatment was rougher than that of non-treatment thigh when comparing SWI images between left and right thighs. It implies that the structure of scar might become fluffy and the composition of capsular contracture might change. The results also indicated that SWI technique was superior to TSE-FS technique in evaluating the capsular contractures.

The assessment of pathologic sections for shock wave treatment group and control group of capsular contractures in this animal model is shown in Table I and II. Figure 3 and figure 4 show the pathologic findings including vessel angiogenesis and myxoid changes after shockwave treatment at 40x and 400x, respectively. Figure 5 shows the pathologic findings including vessel angiogenesis, myxoid changes and some fibrosis after shockwave treatment.

It was found that all four scars became thicker after shock wave treatment (4/4, 100%). The mean capsular thickness was 0.188 ± 0.025 mm in the control group, and 0.375 ± 0.15 mm in the experimental group. Significant change of myxoid of capsule had been found for both shock wave treatment (4/4, 100%) and control groups (3/4, 75%). Furthermore, the changes of myxoid were two positive and two strong positive in the experimental group. Significant difference of vascular proliferation had also been found between the shock wave treatment (3/4, 75%) and control groups (1/4, 25%). Lymphoplasma cells infiltration presented in three cases of the experimental group (3/4, 75%) and in two cases of the control group (2/4, 50%). All cases had inner thin collagen layer in both the experimental (4/4, 100%) and control groups (4/4, 100%). No capsule wall collagen deposition was found in the experimental group (0/4, 0%), while three strong positive in the control group (3/4, 75%). The findings demonstrated that shock wave treatment might be capable to change the structure and composition of capsular contractures. The structure of scars became fluffy and collagen deposition of capsular decreased after shock wave treatment, therefore, the formation of scar decreased. The results confirmed the findings in MR images.

IV. Discussion and Conclusion

Shock wave therapy is used in sports medicine and rehabilitation for powerful tissue healing efficiency. The setting of shockwave treatment is 2~2.5 bar, 3000 shots and 8~12 times in routine treatment of tendon fibrosis. The choice of the settings of the shock wave exposure in our animal model is based on the rabbit's weight and tissue depth. There is no reference for the setting.

The findings demonstrate that shock wave treatment is capable to change the structure and composition of capsular contracture. The structure of scar will become fluffy or collagen deposition of scar will decrease after shockwave treatment, hence, the formation of scar will decrease. Increased myxoid and decreased collagen deposition has also been found in the experimental group. SWI technique is superior to TSE-FS technique in evaluating the capsular contractures. Shock wave treatment has been verified that it can relieve patients' pain. It might provide clinical doctors an alternate way to treat capsular contractures and avoid persecution of secondary surgery. Various treatment protocols will be tested, i.e. changing shock wave intensity and number of shocks, to find an effective treatment protocol in the future.

TABLE I. Assessment of pathologic sections postmortem for shockwave treatment group of capsular contractures

	ScarTh	MyCh	VasPro	LympCI	InTL	CapsCD
1	0.3	✓	✓	✓	✓	×
2	0.5	✓✓	✓	✓	✓	×
3	0.2	✓	×	×	✓	×
4	0.5	✓✓	✓	✓	✓	×

* ScarTh: scar thickness (mm), MyCh: myxoid change, VasPro: vascular proliferation, LympCI: lymphoplasma cells infiltrate, InTL: inner thin layer, CapsCD: capsule collagen deposition.
* ✓ means positive; ✓✓ means strong positive; × means negative

TABLE II. Assessment of pathologic sections postmortem for Control group of capsular contractures

	ScarTh	MyCh	VasPro	LympCI	InTL	CapsCD
1	0.2	✓	×	×	✓	✓
2	0.2	✓	✓	✓	✓	×
3	0.2	×	×	×	✓	✓
4	0.15	✓	×	✓	✓	✓

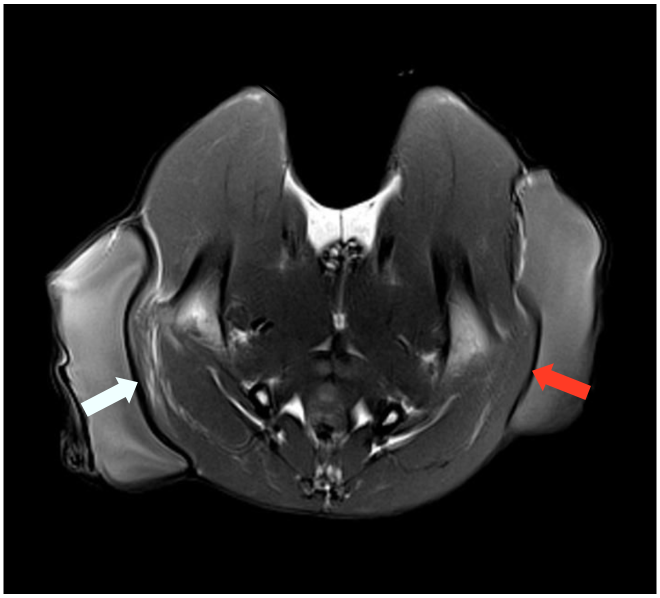


Figure 1. TSE-FS T2W image after shock wave treatment (white arrow indicates treated side and red arrow indicates untreated side).

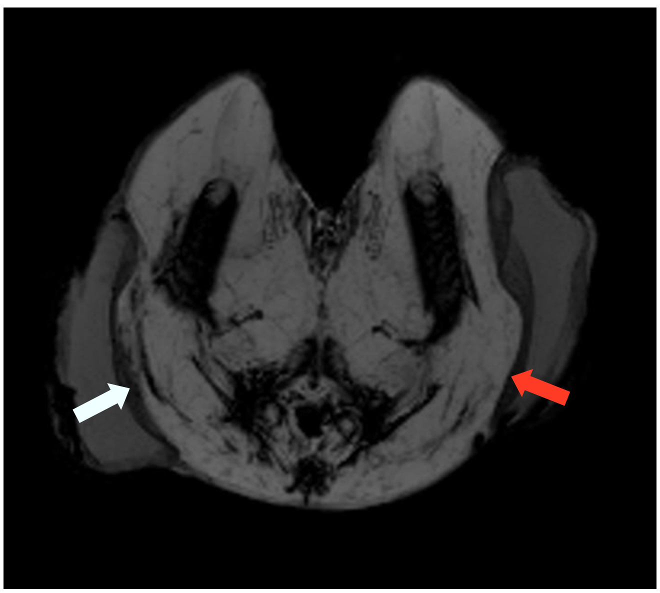


Figure 2. MR SWI-mIP image after shock wave treatment (white arrow indicates rougher surface of the muscle layer at treated side and red arrow indicates smooth surface at untreated side).

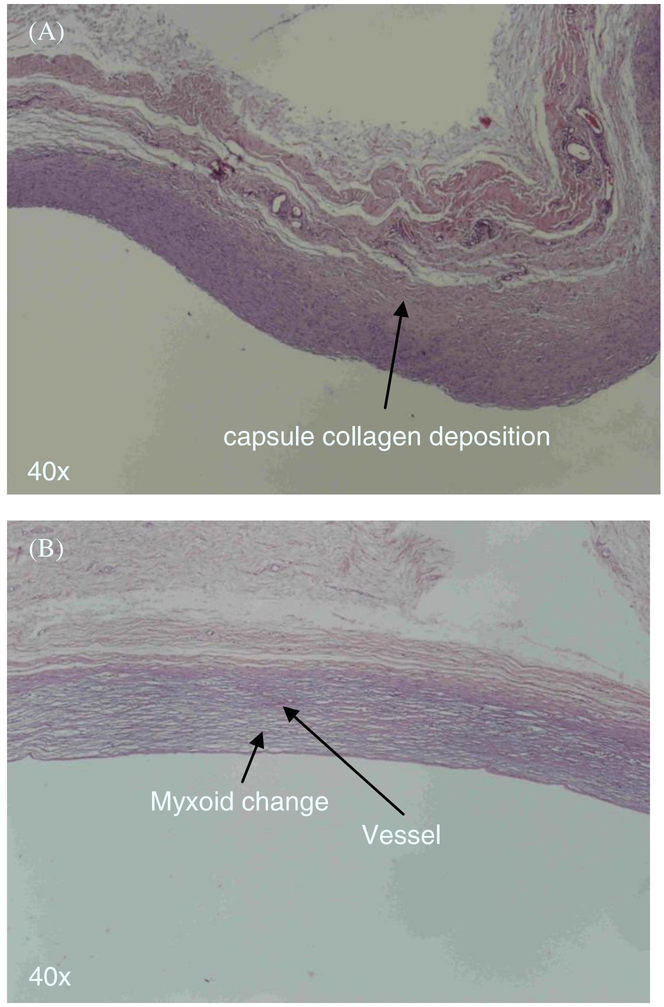
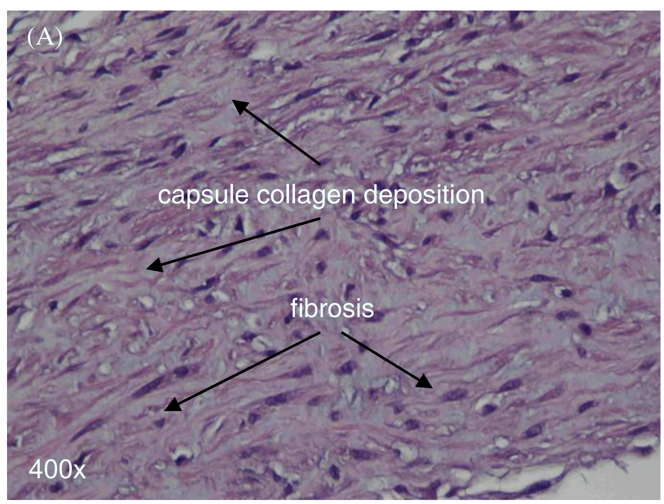


Figure 3. Pathologic sections postmortem (A) Untreated: showing capsule collagen deposition, (B) treated: showing vessel angiogenesis and myxoid changes at 40x.



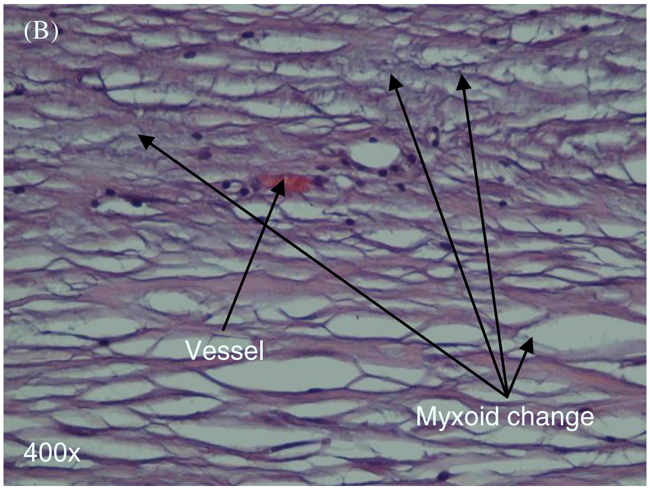


Figure 4. Pathologic sections postmortem (A) untreated: showing capsule collagen deposition and fibrosis, (B) treated: showing vessel angiogenesis and myxoid changes at 400x.

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