ESWT Treatment of Compromised Clavicle Fracture Near Lung Tissue (Slezak et al., 2023)

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Introduction

Treatments with lung tissue in the treatment area have long been considered contraindications for extracorporeal shockwave therapy (ESWT) thus limiting the therapies' regenerative scope of application. This recommendation has been due to the potential tissue damage associated with cavitation induced pulmonary capillary bleeding which may occur at significant distances from the therapy site. In contrast, we consider the potential benefits of ESWT for near-lung bone fractures. A delay or failure to heal is the most common possible complication in clavicle fractures, especially in cases primarily treated conservatively. As the current standard therapy, surgical revision achieves good healing results, but are associated with potential surgery-related complications. Shockwave therapy proposes a comparable non-invasive alternative over surgical intervention while avoiding complications.

Material & Method

A prospective open clinical study was conducted on the efficacy of shockwave therapy in compromised, delayed, or non-union fractures of the clavicle. This retrospective monocentric study compares focused, electrohydraulic ESWT-treated fractures with traditional surgical outcomes. To assess safety and evaluate in-situ ESWT pressure fields during the therapy, a comprehensive three-dimensional computational simulation was performed. Based on applicator reference data, computer simulations provide insights into wave propagation and pressure zones about the lungs thus allowing for safety-guidance based on established ultrasound threshold parameters.

Results

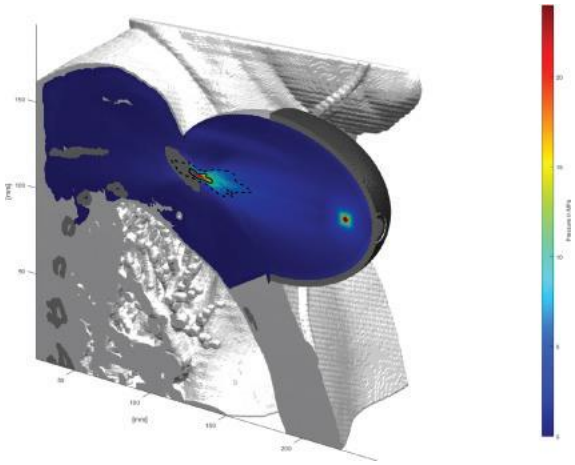
Three months post treatment 46% of the shockwave treated group showed consolidation which is similar to the healing in the surgical group. At the six-month time point both groups achieved healing in three quarters of the patients. ESWT treatments took significantly less time, incurred lower costs, and had no serious complications compared to 19% of the case in the surgical group. The latter further indicates that no evidence was found that lung tissue was damaged during the shockwave treatments. This is further supported by numerical simulations of the treatment which shows the mechanical index of tensile waves to be below FDA approved thresholds at all locations in the vicinity of the lungs.

Table 1

Outcome	ESWT (n = 28)	Surgery (n = 21)	p-Value
After 3 months			
Healed	13 (46%)	9 (43%)	>0.9999
Not healed	15 (64%)	12 (57%)	
After 6 months			
Healed	21 (75%)	15 (71%)	0.7172
Not healed	7 (25%)	3 (14%)	
Lost follow up	-	3 (14%)	
Complications			
Complications	0 (0%)	4 (19%)	0.0282 *
No complications	28 (100%)	21 (81%)	

Patient outcomes over time for ESWT and Surgical intervention

Figure 2



Simulated ESWT pressure fields in and about the therapy zone extending to the lungs.

Discussion

We show that based on numerical simulation and a clinical evaluation that shockwave treatment of for mid- and lateral-clavicle fractures is a safe and effective alternative. ESWT yields good healing results comparable to the surgical treatment, while avoiding surgery-related risks and complications. The presented two-pronged assessment of computational modelling and clinical evaluation allow for a systematic evaluation of potential additional future ESWT treatment sites about the lungs with excellent health outcomes while promising substantial health-care cost saving.

Technology: Focused electrohydraulic Shockwaves
Device and Manufacturer: Orthogold 280C, MTS Medical UG, Konstanz, Germany.
COI: No conflict of interest.

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Study Performance: **ortho**wave280