A Novel Multifunction Device Delivering Cyclic Therapies for Frozen Shoulder

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This paper examined the acute issue of frozen shoulders as an area for market discovery and opportunity. 11 current treatments and standards of care have been analyzed by reviewing their advantages and disadvantages, which showed signs of ineffectiveness and/or substantial risks. Thus, 2 key opportunities for treatment emerged: enhancing existing treatments or developing innovative new ones. Through interviews and surveys with 2 healthcare providers and 29 patients, the needs of a customer have been identified as they shared their experiences on frozen shoulders, treatments used and their effects, and their thoughts on a multifunction device. The device was a proposed solution created through innovation and a combination of modalities, specifically, acupressure and heat, cold, and massage therapy. The results demonstrated the effectiveness of heat, cold, and massage therapy especially when combined into a unit, indicating that a device integrating these modalities would significantly aid in the healing process. Additional treatments, such as red light therapy and percussion, were suggested in the interviews as potential features of the device. An original image of the frozen shoulder device was created, which included buttons and features based on the responses and feedback. The findings encouraged further research on the combined effectiveness of cyclic and intermittent therapies—specifically acupressure, percussion, red light, massage, heat therapy and cold therapy—for non-prescription treatment.

Introduction

Shockingly, 2 to 5 percent of the global population[1] is currently experiencing an excruciating pain in their shoulder. This condition, known as frozen shoulders, is becoming increasingly prevalent worldwide due to the rising rates of chronic diseases such as diabetes and cardiovascular disease[2] . Simultaneously, the elderly population is also increasing, causing a proportional positive trend with the prevalence of frozen shoulders[3]. Originally known as 'adhesive capsulitis', the condition has been dubbed 'frozen shoulder' since 1934, which captures the significant loss of motion in the shoulder[4]. Frozen shoulders can persist for up to 3 years[5] and typically affects individuals aged 40 to 60, with women having 4 times greater risk than men[6]. In this age group, inflammation occurs around the tissues of the shoulder, causing "severe pain and stiffness that develops gradually, worsens, and then resolves" throughout the 3 stages: freezing, frozen, and thawing stage[7].

The freezing stage lasts from 2 to 9 months, during which inflammation begins, and the shoulder slowly loses its range of movement[3]. In the frozen stage, the shoulder stiffens more dramatically, reducing mobility and pain, which lasts from 4 to 6 months[7]. In the thawing stage, the shoulder slowly heals, but it can take from 6 months to 2 years for full recovery[3].

Frozen shoulders have 2 classifications: primary and secondary[8]. Primary classification indicates that the condition arises from an unknown cause; secondary classification, on the other hand, consists of 3 subcategories: intrinsic, extrinsic, and systemic[8]. These categories are based on the diagnosed root cause health issue that impacts a person developing frozen shoulders[8]. The intrinsic–originating "within a body, organ, or part"[9]–subcategory suggests that an existing problem within the shoulder, such as rotator cuff and biceps tendinitis[8], causes frozen shoulders. The extrinsic–originating "outside of a body, organ, or part"[10]– subcategory refers to health issues outside of the shoulder such as cervical radiculopathy and heart attack[8]. Systemic frozen shoulders are associated with systemic diseases, which includes diabetes, tuberculosis, and Parkison's disease[11]. Despite differences in leading causes, Jeff Lombardi, PT, DPT (Prisk Orthopaedics and Wellness, Monroeville, PA) stated in an interview, "these classifications do not alter the types of standards of care used to treat their frozen shoulders".

The shoulder is consisted of three joints (glenohumeral, acromioclavicular, sternoclavicular) and one floating joint (scapulothoracic)[12]. The glenohumeral joint, also known as the ball-and-socket joint, is primarily used to perform movements and daily activities with a comparatively greater range of motion; for example, simple tasks like reaching for items utilizes the glenohumeral joint[13]. The glenohumeral joint is formed by the head of the humerus, the glenoid fossa of the scapula, ligaments, joint capsules, and muscles[14]. Ligaments include the superior glenohumeral ligament, middle glenohumeral ligament, and inferior glenohumeral ligament that serves as stabilizers to the joint capsule[14]. The glenohumeral joint

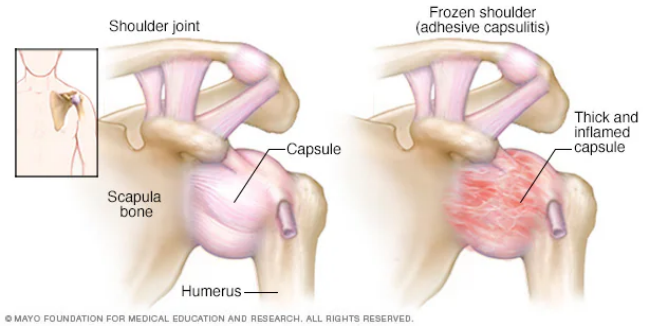

Fig. 1 Affected Area in Shoulder Joint Image from Mayo Clinic presenting a visualization of the shoulder when experiencing frozen shoulders

Source: "Frozen Shoulder." Mayo Clinic, Mayo Foundation for Medical Education and Research, 19 Aug. 2022, www.mayoclinic.org/diseases-conditions/frozen-shoulder/symptoms-causes/syc-20372684.

capsule could be separated into three main regions: anterior, superior, and posterior[14]. In a frozen shoulder, the joint capsule is primarily affected, restricting its anterosuperior capsule that limits "external rotation in the adducted shoulder"[15], anteroinferior capsule that "produces restriction of external rotation in the abducted shoulder"[15], and posterior capsule that "reduces internal rotation of the shoulder"[15].

Thus, with the joint capsule of the glenohumeral joint mostly restricted, frozen shoulders create countless challenges in daily life, even in basic tasks such as sleeping, driving[16], "showering, dressing, and cooking"[17]. Studies have shown that inflammation worsens at night, causing sleep to be unbearable[18]. People found it impossible to get quality sleep and often suffered from "severe sleep deprivation"[18], leading to negatively impacted mental health and weakened immune system.

The aim of this research was to conduct market discovery in the field of frozen shoulders by exploring standards of care and the ideas/experiences of experts in the field while looking for opportunities to positively impact this disease state; in particular, a multifunction therapeutic device was proposed that combined the standards of care: acupressure, heat therapy, cold therapy, and massage therapy. To determine the multifunction device's position amongst the frozen shoulder treatments and standards of care, the research first analyzed the overall market size and the various treatment segments. The research then evaluated different treatments to assess their effectiveness in practice and discussed their advantages and disadvantages. The modalities and needs for both healthcare providers and experienced patients with the diseased state were discovered through interviews and surveys. Survey responses may be biased and subjective as influenced by personal experiences, and due to constraints on the number of participants surveyed, data is limited. The focus was to understand potential improvements in care, to enhance outcomes and treatments with innovation, improved utilization of existing modalities, and optimize cyclic techniques.

Market Dynamics

In the United States, approximately 2 to 5 percent of the population experience frozen shoulders[19]. This percentage makes up over 9 million Americans who suffer from this condition[20].

Today, the treatment options for the frozen shoulder population range from surgery to physical therapy. For the majority, over 90% of patients seek nonsurgical treatments, with physical therapy as the most popular[21]. Nevertheless, the rising likelihood of frozen shoulders is driving growth across all treatment markets such as the physical therapy, surgical, and injection market.

Physical therapy today is the dominant treatment due to its proven effectiveness in most cases. In fact, along with home remedies, physical therapy is a first-line treatment chiefly because of its nonsurgical nature[3]. In 2024, physical therapy had a market size value of $47.59 billion and is projected to reach a revenue of approximately $62.33 billion in 2030[2]. The market is distributed across outpatient clinics, home healthcare agencies, and hospitals ([2]. Particularly, driven by better facilities and advanced medical equipment hospitals provide, physical therapy would lead to a simultaneous "rise in the hospital segment of frozen shoulder syndrome market"[3].

Surgical treatments generally have the highest costs among various types of healthcare, which can limit their market growth[3]. This restriction could be explained with one factor: capitation healthcare, where the patient pays a fixed amount despite the amount of sessions or type of service. As a result, providers may be incentivized to avoid high-cost treatments like surgery to stay within their budget, potentially affecting the availability and growth of surgical services. However, with advantages such as minimally invasive procedures and future technological advancements, the surgical market is anticipated to rise[3]). For example, in 2022, the global market size of orthopedic devices in general is $60.12 billion, and it is projected to reach $88.57 billion by 2031[22].

Injections, or specifically corticosteroid injections, have become an on demand innovative treatment as healthcare systems are recovering since Covid-19 and the Russian-Ukrainian War[23]. Corticosteroid injections is a primary type of joint injections[24]; thus, by analyzing the joint injection market, it is anticipated to reach $12.36 billion by 2032[25]. A factor of this positive trend can be attributed to patient's demand for natural and nonsurgical approaches, with injections fitting this need perfectly due to their minimally invasive nature and effective pain management[25].

Treatments/Standards of Care

In the field of frozen shoulders, a variety of treatments have been utilized by patients and/or prescribed by physicians. Treatments include: Steroid Injections, Physical Therapy, Massage Therapy, Acupressure, and Hydrodilatation[26]. Common minimally invasive surgical treatments are Shoulder Manipulation Under Anesthesia (MUA) and Arthroscopic Capsular Release[27]. There are other treatments such as nerve stimulation, medication, acupuncture, and home remedies, but will not be discussed in this paper. In numerous cases, however, despite the variety of treatment methods available, "a majority of patients never regain the full range of motion they had before"[28].

Physical Therapy

Physical therapy for frozen shoulders aims to increase the shoulder's range of movement and reduce pain through a variety of exercises and treatments based on each stage. In the freezing stage (first stage), "range-of-motion exercises", manual therapy, and modalities (heat and ice treatments) are utilized with the help of a physical therapist[29]. A physical therapist may also recommend a home-exercise program and refer patients for injections or medications that provide short-term pain relief[29]. In the frozen and thawing stage (second and third stage), a physical therapist may use manual therapy, stretching techniques, and strengthening exercises in the thawing stage[29].

Physical therapy is successful for over 90% of the time, yet may still "take up to a year to gain back all lost shoulder function"[30]. However, physical therapy requires sessions that can last from 1 to 6 weeks with a consistent frequency of 3 times per week[30]. In worse conditions, it can take "up to six months or more" sessions[31]. For each session, patients with insurance copay $20-$60[32]; without insurance, patients are expected to pay anywhere from $80-150 per session[32].

Additionally, home exercises are also necessary to enhance the healing process[33], requiring consistency throughout the week. Thus, for many people, due to cost and time requirements, patients, on the majority, have a low compliance rate thus impacting their success.

Steroid Injections

Steroid injections, also called corticosteroid injections, are injected in the shoulder to provide short-term pain relief[34]. It is successful in reducing pain for over 95% of patients who use steroid injections, allowing for "increased motion 6 weeks post-injection"[35]. In order to improve the range of motion of the shoulder, home exercise programs must be used in addition to steroid injections[36].

The price of costeroid injections depends on the location and health insurance status; costeroid injections may cost $20-$50 with insurance and $25-300 without[37].

Hydrodilation

Hydrodilation is an injection treatment which utilizes ultrasound guidance, an anesthetic injection to numb the pain, before finally injecting a solution into the joint capsule[38]. The solution consists of a combination of saline, steroids, and lidocaine that "works to expand the joint capsule and break up adhesions"[39]. One may experience a sore sensation for a few days post-procedure[38].

After the procedure, 3 to 4 months of physiotherapy and post-injection stretching is vital for reducing pain and increasing shoulder flexibility ((Frozen Shoulder. Orthosports, https://orthosports.com.au/shoulder/frozen-shoulder/.)). For 70% of people who undergo hydrodilation, their procedure is successful and effectively improves their shoulder's range of movement; however, there is a 2% risk of arm fracture among those who receive this treatment[40].

With a full package of consultation, ultrasound, the main treatment, and post discharge care, the price is approximately $1651[41]. As a result, hydrodilation may be costly for many patients and does not guarantee success.

Massage Therapy

Massage therapy can palliate pain and inflammation, increase range of motion, and accelerate the healing process[42]. Different types of techniques used can serve various purposes, 2 common examples are the deep tissue massage and Swedish massage[43]. Deep tissue massage applies great pressure on specific areas of the shoulder to reduce stiffness; Swedish massage, on the other hand, increases circulation with its "long, flowing strokes"[43].

Massage for frozen shoulders can range in price based on the types of massage, duration, and location. For instance, for 45 minutes, the cost is around $90[44]. Clearly, massage therapy is on the cheaper end and its variety of techniques can be tailored to different patients, allowing for higher means of success.

Acupressure

A Chinese technique, known as acupressure, works by applying pressure from the fingertips to specific spots on the body. In the case of a frozen shoulder condition, acupressure helps to alleviate stress and increase energy flow in the shoulder[45]. These specific spots to press on are called acupoints, which could also be massaged in circular motions[45]. Acupressure may be contraindicated in areas that have scar tissues, wounds, and rashes, so it is advisable to avoid those areas[45]. Success rates and prices are not well published as experts agree that "Research into the health benefits of acupressure is in its infancy, and more well-designed research is needed to determine how effective the approach is"[45].

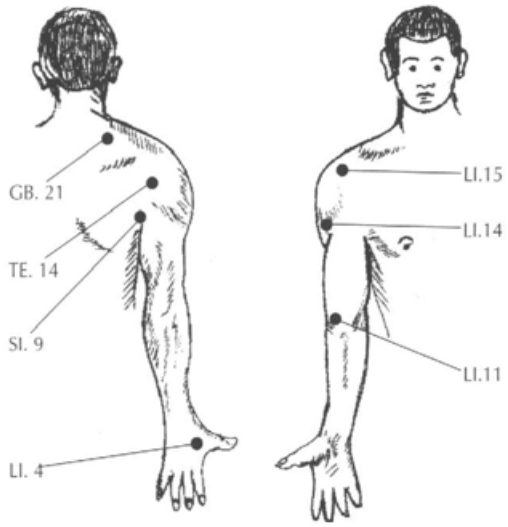

Fig. 2 Acupoints on the shoulder

Shoulder Manipulation under anesthesia (MUA)

Manipulation under anesthesia strives to increase the range of motion of a patient's shoulder. It requires the patient to be fully anesthetized so doctors can move the shoulder with an attempt to "stretch, tear or break the scar tissue"[46]. In order to maintain and improve progress, consistent physical therapy and an "intra-articular steroid injection"[46] is required after the procedure.

Shoulder manipulation under anesthesia has a success rate of over 85%[47]. Yet, this also leaves 15% of patients with comorbidities such as arm fracture, shoulder dislocation, and nerve damage[46]. Additionally, 14% of patients who use MUA require re-intervention[46]. This treatment is contraindicated for elderly individuals, diabetics, and those with osteoporosis[46]. The average cost of manipulation under anesthesia is an average of $1172.25, which includes medication, pre-procedure testing, and the surgical procedure[48].

Arthroscopic Capsular Release

As a minimally invasive surgery, arthroscopic capsular release inserts a radiofrequency probe, after creating 3 small incisions, which utilizes the "waves to cut the tissue capsule that surrounds the shoulder joint"[49]. After the procedure, the incisions are closed with sutures and the shoulder is bandaged[49]. However, for the purpose of preventing the build up of scar tissue and improving the shoulder's range of movement, one must wear a splint on their shoulder and undergo physical therapy after 1 to 2 weeks of the procedure[49].

Arthroscopic capsular release is successful in 86.2% cases[50] especially since the small incisions "minimizes the risk of blood loss and infection"[51]. Though generally safe, potential risks such as infections, blood clots, and damaged blood vessels may arise[13]. Along with higher risks, arthroscopic capsular release also carries higher costs as the procedure ranges from around $6,000 to $10,000 pertaining to the location[52].

Figure 3: Treatments/Standards of Care Pros and Cons
This table displays the general benefits and disadvantages of modalities in physical therapy modalities, surgical fields, and injections fields.

Treatment	Pros	Cons
Physical Therapy	• Nonsurgical	• Requires consistency
	• Individualized treatment plans and learn stretching techniques[53]	• Aggressive stretching may lead to adverse effects[54]
		• "physical therapy has not proven to be effective for this particular condition"[55]
Steroid Injections	• Nonsurgical	• Short term relief[56]
	• Effective short-term pain relief and increase the range of motion[56]	• Side effects: pain, swelling, irregular periods in women, rash, and headaches[57]
Hydrodilation	• Significant improvements[38]	• Potential risks (e.g., nerve injury, bleeding, and infection)[38]
Massage Therapy	• Enhance circulation and alleviate pain[58]	• Temporary effectiveness[58]
Acupressure	• Nonsurgical and drug-free	• Contraindicated in areas that have scar tissues, wounds, and rashes[45]
	• Increase circulation, improve mobility, relieve tension, and reduce pain[45]	
Shoulder Manipulation Under Anesthesia (MUA)	• Improved range of motion[47]	• Surgical with risks
	• Reduced pain[47]	• Contraindications for elderly, diabetics, and those who have osteoporosis[47]
		• Requires physical therapy and injection after procedure[47]
Arthroscopic Capsular Release	• Minimally invasive due to small incisions[49]	• Potential risks (e.g., blood clots, infection, damaged blood vessels and injured nerves)[59]
	• Low risk of infection[49]	

Summary of Healthcare Provider Treatments

Today's standards of care, including physical therapy and arthroscopic capsular release, generally demonstrate a good success rate. However, these treatments can be difficult to access, expensive, and require consistent adherence. Additionally, they carry potential risks such as damaged nerves, bleeding, and infection.

Over The Counter Competitors in the Market Today

Currently, there are single treatment devices for the assistance of frozen shoulder recovery. These devices include shoulder pulleys, shoulder braces, and ice, heat, and light therapy.

Heat therapy is a common modality for frozen shoulders, where heat is applied to the shoulder, usually 15 to 20 minutes each time[60], 3 to 4 times a day[61]. It is most effective in the frozen and thawing stage due to its ability to widen "blood vessels to increase blood flow to the injured area"[60] and can also be used before stretching to loosen up the shoulder[62]. Since heat therapy treatment is not often used alone, success rates are not well published.

Heat therapy devices are commonly in the form of heat pads that aim to increase blood flow and circulation[63]. Prices of heat therapy devices can range from $14 to 100$ depending on the quality and its features[64]. For instance, some heat devices are rechargeable and cordless, while others may offer a 3 heating setting to adjust the intensity of the heat[64].

Cold therapy is best used in the freezing stage[60] and serves a purpose to reduce inflammation and soreness. Similar to heat therapy devices, cold therapy devices also include shoulder pads. However, these shoulder pads usually include a cooler freeze kit to create a sustaining coolness[65]. On average, cold therapy devices cost between $100 to $300[65] which is significantly more expensive than heat therapy devices.

Light therapy pads use red light therapy, declaring it as an effective method for a natural healing process. An example would be the HealthLight Red Light Therapy Shoulder Pad, which offers 5 of these devices that vary in pad size and shape[66]. Red light therapy devices are more expensive compared to other devices; for a shoulder wrap size, it can range between $100 to $500[67].

Shoulder braces promote proper healing by preventing jarred movements, which can result in damaging and tearing the shoulder. Some shoulder braces have heat or cold options from numerous brands like Shock Doctor and Sparthos[68]. Prices can range from $25 to 100$ based on its features and functionality[68].

Shoulder pulleys can be used during physical therapy that aim to strengthen shoulders and its range of motion. Several brands that offer shoulder pulleys are Fanwer, ATENTO, and Vive[69]. Depending on the quality, shoulder pulleys range in price from $15 to $25[69].

Combination Therapies

A state-of-the-art combination therapy was a variation that combined brisement therapy (involves injecting a large volume of fluid into the joint to stretch out the capsule), nerve block (applied to reduce pain during brisement), and physical therapy[70]. It aimed to address both pain and range of motion issues, expedite relief, and even became a "first line of treatment for frozen shoulder"[70] to many providers in Cleveland Clinic.

Figure 4: AFDEAL Cordless Shoulder Brace
This image showed the AFDEAL Cordless Shoulder Brace, which combined modalities. Source"[72]

The variation was contraindicated for patients with diabetes as the steroid injection in the brisement process might create rises in blood sugar leve[70].

Devices that combined modalities for frozen shoulder could be exemplified by the CREATRILL Massaging Heated Shoulder Wrap Brace, Shoulder Heat Therapy Wrap Heating Pad, which combined heat therapy and vibration with adjustable sizes, "3 temperature settings and 3 vibrating modes"[71]. Reviews regarding the features were positive rather than the performance of the device[71].

Though not targeted directly to frozen shoulder conditions, the AFDEAL Cordless Shoulder Brace combined heat and massage therapy as well as vibrations[72]. It includes an LED display to choose the most comfortable temperature. There were positive reviews regarding the feature, yet the adjustability and comfortness of wearing the device was heavily criticized[72]. Massage function received mixed reactions, as some felt it was too "weak" and thus, ineffective[72].

Methods

For this research, primary and secondary research methods were employed. With respect to primary, qualitative interviews and specifically designed surveys were the methods utilized to understand the needs of patients and physicians. Secondary

research was also executed to understand standard of care, market opportunities, trends, and parallel markets. A multifunction device was proposed as a potential solution combining heat therapy, cold therapy, massage therapy, and acupressure features.

Patient and physician feedback could determine the advantages/disadvantages of today's standard of care and whether the proposed solution would be feasible. Of the 31 interviewees, 2 were physicians and 29 were patients.

In executing the interviews and surveys, the interviews were conducted via the Zoom platform. Surveys, on the other hand, were created in Google Forms and sent out to frozen shoulder social groups.

For patients, the survey covered 4 major categories: their experience with frozen shoulders, the treatments utilized, their thoughts on specific modalities (heat, cold, and massage therapy), and their opinion on a multifunction device to treat frozen shoulders.

For physicians, the survey covered 4 components as well: the treatments prescribed, patient feedback, their thoughts on specific modalities (heat, cold, and massage therapy), and their opinion on a combined multifunction device to treat frozen shoulders.

Participant data was kept confidential by only including gender as a demographic and their responses to the survey questions in the tables. Emails and names of participants were also collected but not reported. Physicians were noted as Physician A and Physician B to protect patient anonymity. All feedback was included, ensuring that the results were unbiased and that each participant's thoughts were considered carefully.

Results

The results below are summarized data for the interview and survey process, which includes feedback from physician interviews and experiences shared by patients with frozen shoulders. The interview data were put into tables, pie charts, and bar charts to clearly visualize the standards of care used by patients and how effective they were.

While treatments are listed separately, many patients used a combination of treatments.

Based on the data we collected, some combination of heat, cold, and massage therapy was used by 34% of patients.

Summary of results: The physicians comprise 2 distinct specialties, physical therapy and occupational therapy, offering a broader and more diverse perspective on feedback. Both physicians's prescribed treatments have reached success and positive feedback from their patients. When focusing on heat, cold, and massage therapy, both heat and cold therapy received positive feedback, but there was mixed feedback regarding massage therapy as one physician mentioned the possibility of exacerbating the condition. Further, the physicians were

Figure 5. Individual Physician Feedback

This table displays the feedback and responses of two (2) frozen shoulder physicians on treatments and a multifunction device who were interviewed.

Physician	A	B
Demographics	Male	Female
Occupation	Physical therapist (8 years of experience)	- Manual Capsular Dissection (MCD) Frozen Shoulder Practitioner (7 years of experience) - Osteopathic Manual Practitioner (4 years of experience) - Certified Full Body Trigenics Practitioner (14 years of experience) - Body Trigenics Instructor (10 years of experience) - Physiotherapist (46 years of experience)
Summary of Patient Feedback Under Care	- Radiating pain down to arm all the way to elbow, can't lift overhead, can't grab things, huge inconvenience, throbs in night	- Debilitating pain that worsens at night and the inconvenience on daily life - Sense of hopeless and depression that leads to suicidal thoughts.
Treatments Prescribed	Physical Therapy (Modalities and Home Care Program)	MCD frozen shoulder procedure combined with myoneural rebalancing of aberrant neurological input
Patient Feedback on Prescribed Treatment	- Benefits in relief, healing, and strengthening	- Brought hope into life especially family life - Wished procedure was done sooner and was available in the United States
Feedback on multifunction device for frozen shoulders	- Should not be used for massage as it can't control intensity based on patient emotion - Potential functions: Acupressure, red light therapy, and Vibrations/percussions	- May not address adhesions or fibrosis of the capsule - May provide relief for easier cases

Figure 6. Summarized Physician Feedback for Hot, Cold, and Massage Therapy

This table displays the summarized feedback for hot, cold, and massage therapy of the two (2) physicians.

Hot Therapy	- Used for all stages, especially chronic stages
Cold Therapy	- Used to reduce pain of the synovitis in the freezing stage or soreness after stretching
Massage Therapy	- Used for all stages, providing slight increase of range and short term relief - Risk of worsening condition

Figure 7. Patient Feedback on Frozen Shoulder Experience
This table shows the patients' feedback (out of 29) and the percentage

Experience	Patient Percentages	Feedback
Pain and Limited Range of Motion	100%	- Dull pain for 24 hours a day - "Arm felt dead but still attached" - Chronic fatigue
Affected Daily Activities	69%	- Can't reach behind to grab items - Struggle to wash and tie hair - Painful to drive and cook - Hard to put on clothes - Stopped playing piano - Struggling to unload dishes - Unable to fasten seatbelt
Difficulty Sleeping	52%	- Pain at night disturbs sleep - Hard to find a comfortable position - Loss of sleep
Zingers[1]	17%	- Severe and horrible sharp pain from shoulders
Got Depression	3%	- Felt life was taken away from them due to ineffective treatment

[1] A shocking and painful sensation

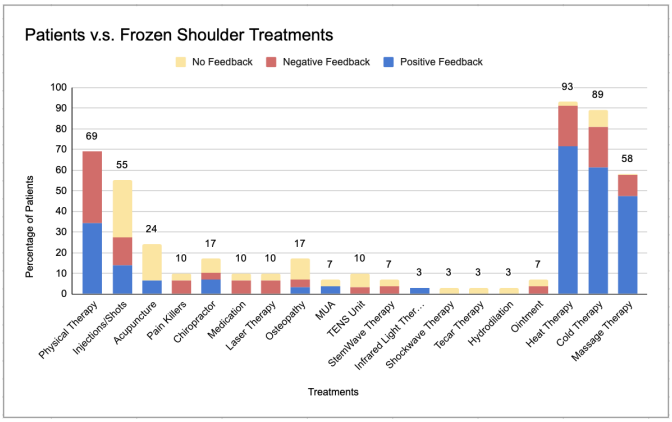

Figure 8. Frozen Shoulder Treatments Patients Used
This chart displays the frozen shoulder treatments patients named in their response as well as the percentage of patients (out of 29) that used them.

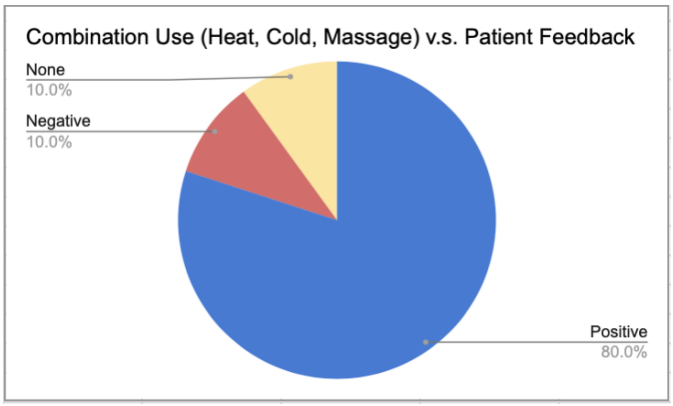

Figure 9. Combination of Heat, Cold, and Massage Therapy
This chart shows the 34% patients who used a combination of heat, cold, and massage therapy and whether they had positive, negative, or no feedback.

Figure 10. Patient Preference of Device
This table displays the patients' preference between a multifunction device described in the research or physical therapy, the most common treatment for frozen shoulders.

Preference	Percentage of Patients	Reason
Multifunction Device	31%	- Convenient - Requires less travel - Avoids driving which is painful
Physical Therapy	31%	- Have all necessary tools and equipment - Capable of answering arising question
Both Multifunction Device and Physical Therapy	17%	- Both treatment methods have their own benefits
Uninterpretable Feedback	20%	Not Applicable

inquired about their thoughts on a multifunction device for frozen shoulder. Physician A mentioned that because a device is nonhuman, it might not be best for soft tissue work due to its lack of control in intensity based on the patient's experience and emotions, yet features such as vibrations/percussions and acupressure would work. On the other hand, Physician B suggested that the device could be only used for less severe cases. For patients, the demographics of all patients were female who reported limited mobility and functionality, continuous discomfort down the arm, and general pain specifically at night when describing their experience with frozen shoulders. Some also mentioned additional complications, such as depression. A broad scope of treatments were highlighted in the survey with a majority of patients opting for physical therapy and injections. The data collected and summarized in the tables above conveyed that heat, cold, and massage therapy were also used by most patients and effectively provided relief.

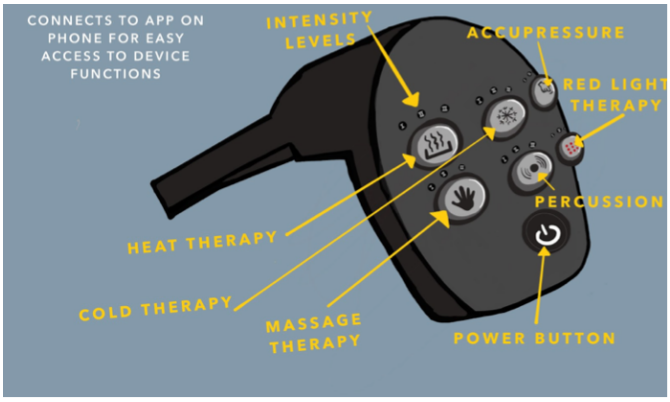

Figure 11. Multifunction Device
This image created for the purpose of this paper is a model of the multifunction device with its features and buttons.

Discussion

The objective of this research was to explore the market of frozen shoulder by examining the various standards of care in frozen shoulder and gathering insights from experts. The paper discovered whether there are opportunities to improve treatment for this condition by proposing a multifunction device and evaluating its potential based on a comparison to market analysis and feedback from surveys.

First, the continuous growth of frozen shoulders globally indicated a positive trend in all treatment markets such as the physical therapy, surgical, and injection market. However, due to reported inefficiencies in current standards of care, life-threatening side effects, expensive prices, and the need for frequent sessions to sustain progress, there appeared to be opportunities to increase care with a multifunctional therapeutic device that combined therapeutic modalities in a more controlled and predictable manner. For example, current combination therapies and devices relating to frozen shoulders were introduced, which demonstrated the practicality of utilizing a multifunction device to improve frozen shoulder pain. The proposed device also had features that paralleled that of the current devices, such as intensity levels features (or "modes"), which received positive feedback from patients regarding the functionality. The intensity level features for each modality button (see Fig. 11), could allow the user to select the most suitable option for their condition and pain. Additionally, the device could also connect to an app on a phone, enhancing control and easy access to device functions without the need of reaching over to press a button. The tables above (Fig. 5 and Fig. 8) further supported the observation that healthcare providers and patients had consistent feedback on the lack of success from today's treatments, and continuous use of heat, cold, and massage could positively impact the healing of frozen shoulders.

The negative feedback on the severity of frozen shoulders underscored the urgent need for effective treatments, suggesting that innovative solutions could have been particularly valuable. Patients reported dissatisfaction and ineffectiveness with various treatments, from physical therapy to manipulation under anesthesia and osteopathy, further emphasizing the demand for better alternatives.

Specifically for heat, cold, and massage therapy, original features of the multifunction device, heat and cold therapy received a majority of positive feedback, demonstrating that they are essential components for the device. Massage therapy garnered mixed reactions between patients and physicians; while physicians believed massage therapy might pose potential risks, most patients who used massage therapy reported improvement and relief. Thus, massage therapy also proved to be a vital factor of the device. Only 34% of patients used a combination of these modalities, yet 80% of those users reported benefits indicating the potential effectiveness of integrating heat, cold, and massage therapy into a single operating unit. The combination of these modalities would work together synergistically as heat therapy is preferred during the frozen stage and thawing stage, cold therapy is more suitable for freezing stage, and massage therapy helps relieve joint stiffness overall; in other words, the device provided relief treatments that is most effective for each frozen shoulder stage. Besides, if one modality does not effectively address the patient's needs, they could always switch to the other options, allowing the device to be versatile and adaptable.

Acupressure was another originally considered component of the device. Although it was not widely mentioned by other patients, Physician A stated that acupressure would be viable as a feature of the device, underscoring its potential benefits. Physician A also mentioned the practicality of adding vibrations/percussion and red light therapy in the device, opening up additional possibilities to its functionality. The

positive feedback from a patient who used red light therapy further supports the inclusion of this feature, indicating it may contribute to the device's effectiveness. These potential additions could significantly broaden the device's therapeutic capabilities.

When asking patients about their preferences between a multifunction device and physical therapy–being the most commonly used treatment–the data revealed an equal number of individuals opting for each option. This showcased the device's ability to stand in the market, even against strong and well-established competitors such as physical therapy. The market analysis highlighted the growing emphasis on natural and cost-effective solutions, which aligned with the patients' responses as well as the device's potential for home use and patient-centered care. Despite the prevailing growth of physical therapy, challenges patients have mentioned from going to physical therapy sessions or utilizing current standards of care were cost and insurance, which would be quite expensive considering multiple sessions/visits. Besides, access to clinics could be a potential barrier considering transportation fees and the inconvenience of driving as stated by patients. Thus, the device offered distinct advantages: it would be highly convenient and cost effective as it could be used at home and at any time, reducing the need for unnecessary tests and minimizing transportation costs. As a result, they could avoid the discomfort and irritation associated with traveling for treatment.

However, there could be possible drawbacks, taken that users of the proposed device would most likely not reach out to physicians or medical professionals as the device was an "at home" treatment. Without proper guidance, patients might not know what features to use (and at their particular frozen shoulder stage), which would reduce effectiveness if used incorrectly. Patients might also overuse the features, such as applying heat for too long, which could worsen the inflammation consequently.

The research limited its scope to focusing solely on qualitative research as the participants interviewed and surveyed were few, lacking the necessary data for a full quantitative analysis. The participants for patients were all female, which is reasonable as frozen shoulder is more prevalent in women; however, only a female experience could be represented. Having male participants would provide for a wider range of perspectives and experiences. Moreover, surveyees' responses may have potential bias, which could be subjective and influenced by personal experiences. The study did not include a control group indicating that improvements could not be definitely attributed to the combined therapies, in the presence of confounding factors. Furthermore, the study primarily focuses on short-term effects of modalities; therefore, further research on its long-term effects is essential to provide a balanced perspective.

In conclusion, frozen shoulders is a growing condition due to the prevalence of health issues such as diabetes and the elderly population. This positive trend is an indication of a continuous growth in frozen shoulder treatment markets such as physical therapy, injection, and surgical categories. The interviews and surveys with patients and healthcare providers demonstrated an opportunity through innovation to create new technology, which would combine modalities of heat, cold, and massage therapy as well as acupressure and vibrations/percussions. With unique benefits in lower risks from its natural approach and high compliance rate as it can be easily accessible, the multifunction device proved its ability to stand in the market and grow.

To further advance treatment for frozen shoulder, it is recommended to increase the number of participants in both healthcare provider and patient studies to provide more comprehensive data, which is crucial for determining the feasibility and functionality of the multifunction device. Additionally, further exploration into the effective use of combined modalities is essential. Investigating factors such as optimal duration, timing, and sequence of these treatments could lead to more effective and tailored approaches.

Ultimately, this multifunctional device demonstrated its potential to streamline care by offering a cost-effective option that could be used at home, improving accessibility and outcomes for patients with frozen shoulders. It highlights a shift away from traditional physical therapy toward patient-centered care at home.

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