From Post-Traumatic Stress Injury To Sustained Healing:

# A New Model For Care

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Prior to the pandemic, 1 out of every 11 adults were estimated to struggle with Post-Traumatic Stress Disorder (PTSD). The additional burden of psychological trauma beginning in 2020 and the associated human cost of trauma exposure is staggering. PTSD is associated with higher rates of depression, substance abuse, and suicide. Healthcare costs are 2-3 times greater for individuals with PTSD. During this time of unprecedented trauma, we must innovate like our lives depend on it -- because they do.

Though traditional modalities can be effective if patients remain in treatment, they are costly, they may take many weeks or months to take effect, and may not be elected in the first place, leaving the majority of PTSD sufferers stuck in a cycle of non-remission. One of the most promising interventions for psychological trauma, the focus of this white paper, is called Stellate Ganglion Block, or "SGB." SGB involves injecting an anesthetic medication into a bundle of nerves in the neck. SGB targets symptoms like disrupted sleep, surges of anxiety, irritability, hypervigilance, an acute startle response, and difficulties concentrating.

SGB is not new. It has been used to treat physical pain conditions for nearly a century. Thousands of warfighters have gotten relief from their worst symptoms of mental trauma with this procedure, usually within a single session. Yet relatively few trauma sufferers are aware of it. Over the course of the last two decades, SGB for trauma has been the subject of significant clinical research. It has repeatedly been documented as a safe and effective treatment modality. SGB has some specific strategic advantages, and some limitations. Advantages include a no-stigma pathway to relief, rapid relief for many who are treated, no attrition from care, cost savings and increased access to care due to its inherent efficiency, no documented long-term side effects, and no risk of a positive "illicit" drug test.

Limitations include a 10-20% non-response rate, potential complications (although SGB is considered a routine, minimally invasive procedure when performed by a skilled physician), and the potential for patients to view SGB as a "miracle cure." SGB is not best applied as a standalone treatment. When SGB is used in combination with psychotherapy and other mind-body wellness practices, its full power is unleashed. SGB is the "primer" before the "paint" of psychotherapy and other wellness programs.

This white paper reviews the history of SGB, research and clinical development of its application to emotional trauma symptoms, common misperceptions related to SGB, and its potential to address the crisis of globally impactful trauma exposure.

Even prior to the global pandemic, statistics showed that 1 of 11 people in the adult population will develop PTSD during their lifetime, with 8 million suffering in the US. Prior to the emergence of a global pandemic that has caused millions of traumatic deaths, statistics showed that 1 of 11 people in the adult population will develop PTSD during their lifetime, with 8 million suffering from PTSD each year.<sup>1</sup> The additional burden of psychological trauma beginning in 2020 is hard to calculate. As of this writing, in August 2021, over 210,000,000 COVID-19 cases and 4,400,000 deaths have been recorded across the globe.<sup>2</sup> Studies show that between 18% and 36% of people in the post-illness phase of COVID-19 experience symptoms of post-traumatic stress. Recordsetting wildfires have swept across the United States and Canada throughout 2020-2021.<sup>3</sup> The prevalence of PTSD is between 30% and 40% among direct victims of disasters.<sup>4</sup> Social isolation has become our collective "new normal" during the same period of time.

Between 25% and 29% of people in isolation or quarantine for a period of 10 days or longer met the criteria for PTSD.<sup>5</sup> A city-by-city report across the United States found that calls to police regarding domestic violence increased by 10% to 27% between March and April 2020, when most shelter-in-place orders took effect.<sup>6</sup>

#### The Human Cost of Unaddressed Trauma Symptoms

People with PTSD are:

more likely to

die by suicide

individuals with PTSD may be as much as 9.8 times more likely to die by suicide relative to those without PTSD, an association that remained after adjusting for depressive symptoms.<sup>10</sup> Based on data from the Canadian Community Health Survey of more than 35,000 people, another study found a more than 2-fold association between a suicide attempt in the past year and current PTSD, after adjusting for psychiatric and physical disorders.<sup>11</sup> Those who do not die by their own hand often develop additional challenges that derail their lives and limit their potential, to include comorbid depressive disorders and substance abuse.<sup>12</sup>

The human cost of trauma exposure is staggering. Research has shown that

Research suggests that up to 62% of PTSD sufferers go undiagnosed.<sup>7</sup> An estimated 50% of those who face severe trauma do not seek care<sup>8</sup> and among

those who do, remission rates are often relatively low.9

According to data collected by the U.S. Department of Veterans Affairs, nearly 1 in 3 veterans seeking treatment for a substance use disorder also has PTSD.<sup>13</sup> SAMHSA data within the larger population shows that substance use disorders are 3-4 times more prevalent within those who have PTSD.<sup>14</sup> Likewise, a meta-analysis of 57 studies, inclusive of both military and civilian samples, showed a strong association between PTSD and depressive disorders, with a projected co-morbidity rate of 52%.<sup>15</sup>

PTSD is meaningfully related to workforce productivity and quality of life factors, including loss of employment and decreases in general life satisfaction.<sup>16</sup> Trauma leads to symptoms that diminish capacity to experience warm and loving feelings for others (emotional numbness), profound negative changes in our self-image and identity, fears that often limit our enjoyment of pleasurable activities, and other life-altering challenges. Many survivors experience recurrent feelings of helplessness and horror, and may commonly experience crippling panic attacks, feelings of self-blame and shame, chronically disrupted sleep, and relationship conflict with loved ones.<sup>17</sup>

Healthcare costs are 2-3x greater for individuals with PTSD. The human cost of trauma exposure is reflected in healthcare costs, which are 2-3 times greater for those with PTSD relative to non-PTSD sufferers.<sup>18</sup>

During this time of unprecedented trauma, we must innovate like our lives depend on it -- because they do.

#### The Current Landscape of Care

The current standard of care is to offer a combination of trauma-focused psychotherapy and symptom-focused medications, typically an SSRI medication.<sup>19</sup>

#### Common barriers include:

Mental health stigma	
Concerns about receiving a diagnosis	
Reluctance to engage in trauma exposure work	
Initial increase in symptoms for certain therapies	
Drop out from care	
Potentially lengthy treatment courses	
Financial cost of traditional treatment	
Medication-related concerns (side effects, preference to not take medications)	

There are multiple barriers to relief associated with the current model of care. First, prospective patients may need to overcome significant mental health stigma. Individuals must be willing to accede to receiving a diagnosis of a "mental health disorder" and have this diagnosis charted in their medical history.<sup>20</sup> Patients whose occupations are less accepting of mental health challenges may have concerns about the impact of a medically charted diagnosis on their current employment status or future occupational opportunities.<sup>21</sup>

Patients who overcome these initial barriers will need to consider whether they are willing to undergo psychological treatments that require them to confront and discuss their trauma memories with healers they are assigned to work with, usually in the context of time-

limited, trauma-focused therapy protocols. For many patients, it may be asking too much for them to face their trauma while they are in a state of chronic hyper-arousal. Related to this, traditional "first line" treatments will initially heighten the most aversive symptoms of trauma, causing increased panic attacks and difficulties sleeping. This becomes a second serious barrier to relief, as it can lead to drop out from care, or not engaging in care in the first place.

In addition, many patients are not willing to take medications that are offered to them. For some people, a daily medication prescription, while potentially helpful for certain trauma symptoms, can also be an unwanted, continual reminder of their trauma. Others may have concerns about taking medications given the requirements of their jobs. Some may be concerned about side effects of medications, such as loss of sex drive in the case of SSRI medications, or the potential for physiological addiction in the case of benzodiazepine medications prescribed for panic symptoms.<sup>22</sup>

For those who choose to undergo trauma-focused therapies and/or current first line medications, there is often a substantial delay before relief is experienced.

Even the most effective forms of exposure therapy may require several weeks to take effect. In a study that looked at more than 10,000 patients, research showed that half of the patients required 21 treatment sessions (about six months of weekly therapy) to achieve clinically significant gains. In the same study, 75 percent of patients showed meaningful improvement after more than 40 treatment sessions. In other words, it often takes 6 months to a year of weekly therapy to get substantial relief from trauma symptoms.<sup>23</sup> And this process can itself be very hard on patients – leading many of them to drop out of care before achieving relief.

In addition, for some therapies that are widely considered "best practice" treatments, there can be a high rate of attrition, or drop out, from care. For instance, in a randomized clinical trial of 255 female veterans who received prolonged exposure therapy for trauma, nearly 40% dropped out of care and 60% still met criteria for PTSD following treatment.<sup>24</sup>

Though traditional modalities can be effective if patients remain in treatment, they are costly, they may take many weeks or months to take effect, and may not be elected in the first place, leaving the majority of PTSD sufferers stuck in a cycle of non-remission.

In the past couple years, a number of new treatments for PTSD have begun to emerge – based on a new understanding that trauma exposure causes biological changes that can be addressed with biologically-based interventions – to include both non-psychoactive and psychoactive treatments.

### The Launch of a Promising New Treatment

One of the most promising interventions for psychological trauma, the focus of this white paper, is called Stellate Ganglion Block, or "SGB." SGB involves injecting an anesthetic medication into a bundle of nerves in the neck, a few inches above the collarbone, to target some of the most severe trauma symptoms - disrupted sleep, surges of anxiety, irritability, hypervigilance, an acute startle response, and difficulties concentrating. SGB has been used to treat pain related diagnoses for nearly a century – including shingles, complex regional pain syndrome, and phantom limb pain.

Lack of familiarity among many behavioral health providers has led some to refer to this as a "new treatment" for PTSD. In fact, SGB is a novel application

SGB is a novel application of an existing treatment that has been documented since 1926 in medical literature and was documented in 1947 as a treatment for depression. of an existing treatment that has been documented since 1926 in medical literature<sup>25</sup> and was documented in 1947 as a treatment for depression.<sup>26</sup> Even within the field of trauma care, SGB was documented to have an impact on trauma symptoms over 30 years ago, in 1990,<sup>27</sup> and has been proactively deployed for over 15 years, since the first documented trauma-focused case in 2008.<sup>28</sup> SGB has been used in military hospitals, special forces units and select VA treatment facilities. Thousands of warfighters have gotten relief from their worst symptoms of trauma with this procedure, usually within a single session.

Between 2019-2021, there has been a surge of interest in SGB as a treatment for symptoms of anxiety and trauma. This has included completion of a 3-site randomized controlled trial published in a top tier medical journal (JAMA Psychiatry),<sup>29</sup> several features in the media and popular press, including 60 Minutes<sup>30</sup> and WGN-TV,<sup>31</sup> and a documentary film series following the stories of 3 SGB patients that claimed 7 Emmy Awards.<sup>32</sup>

Throughout 2020 and 2021, Stella has launched more than 40 clinics across the United States, with several additional clinics within Australia, to make SGB available to those who suffer from emotional trauma symptoms. SGB has also been the focus of political movements in the United States with lawmakers of all party affiliations in the state of Pennsylvania unanimously resolving with a vote of 202-0 that SGB be made available as a covered treatment option within the national network of Department of Veterans Affairs Healthcare System.<sup>33</sup> Both the VFW, the American Legion, AMVETS National, the Green Beret Foundation, Mission 22, and members of Congress from both parties have endorsed the TREAT ACT which would make SGB available as a treatment option for veterans across the Department of Veterans Affairs Healthcare System.

This white paper will review the history of SGB, research and clinical development of its application to emotional trauma symptoms, common misperceptions related to this new treatment option, and its potential to help resolve our international crisis of unaddressed trauma. The acceptance and use of SGB as a treatment for trauma goes well beyond "adding a new tool to our toolbox" – SGB is the focus of a larger paradigm shift in mental health care towards a new model of care, to be elaborated in this white paper.

#### An Evolution in the Concept of "PTSD"

When Post-Traumatic Stress Disorder was first included in the Diagnostic and Statistical Manual in 1980, it was classified as a mental "disorder."<sup>34</sup> This inclusion of PTSD as a formal diagnosis was helpful in some ways because it signaled a shift towards the understanding that trauma is real, and not "all in one's head." The recognition of PTSD as a definable condition was a critical step in

## 40 clinics

Opened in US between 2020 & 2021. Adding roughly one new clinic a week. supporting many who suffer, to include thousands of Vietnam veterans who were experiencing trauma symptoms following their time in the service.

PTSD has since been identified as one of the most prevalent "invisible" wounds of the wars in Iraq and Afghanistan.<sup>35</sup> A more recent movement, spurred by advances in neuropsychiatry and led by eminent Psychiatrist Frank Ochberg, who coined the term "Stockholm Syndrome," aims to further evolve our collective understanding of post-traumatic stress as an "injury" rather than a "disorder."<sup>36</sup>

We manage 'disorders' while we heal from 'injuries.' Advances in neuroscience suggest that PTS is an injury and it can be healed. The move to conceptualize Post-Traumatic Stress as an "injury" is critical for a couple reasons. First, for many who suffer, the term "disorder" has a stigma attached to the idea of an inherent deficiency. On the other hand, an "injury" is widely seen as a nofault, no-shame challenge without any associated stigma. Second, the concept of a "disorder" often suggests a more permanent condition – something that may go into remission at times, but that has a long-term course. A disorder is more likely to attach itself to an individual's sense of identity. In contrast, an "injury" is often seen as treatable with the right intervention. We often manage "disorders," while we heal from "injuries."

SGB as an intervention for trauma symptoms arose from neuroscience advancements and evolving views of trauma's impact. A neuroscience-informed view suggests that what has been called "PTSD" is in fact a biological injury that can be visualized with advanced imaging machines. The "injury" model of posttraumatic stress (PTS) suggests that trauma is largely a biological condition, with psychological and social components that are maintained by a shift in normal biological functions.

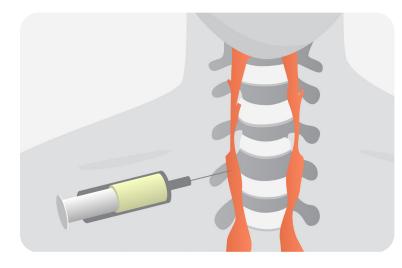
In other words, PTSD is an involuntary, physiological change in the brain that can develop after an individual is exposed to trauma, which often leads to debilitating mental and physical symptoms. Trauma shatters assumptions about safety and changes how we behave as we navigate the world and relationships around us. So, along with a biological injury, there is also a cognitive and behavioral element to non-recovery after trauma exposure.

#### How does SGB work?

As mentioned previously, SGB involves injecting a widely available, commonly used anesthesia (typically Ropivicaine or Bupivicaine) into a bundle of nerves in the neck, called the "stellate ganglion," just above the collarbone. The stellate ganglion connects to the amygdala, the portion of the brain that governs the "fight or flight" system. The injected medication is non-psychoactive – a routinely used anesthetic medication that reduces symptoms associated with chronic sympathetic over-activation. Performed on an outpatient basis, a typical procedure takes about 15 minutes.

Similar to the process used to support countless women who receive epidurals during childbirth, a properly placed injection carries no known long-term side effects.

When performed by a properly trained, board-certified doctor, SGB is considered a safe, routine procedure.



Consistent with the view that PTS is an injury, our baseline functioning may change in dramatic ways after trauma exposure. In some cases, we become stuck in "fight or flight" mode, which can be observed in certain types of brain scans.<sup>37</sup>

Common indicators of this altered biological state include symptoms like disrupted sleep, anger attacks, overwhelming panic, difficulties concentrating, a feeling of constantly being on "high alert", and a strong startle response - in other words, the "hyper-arousal" cluster of trauma symptoms. This writer (Dr. Springer) has referred to this state as "chronic threat response" in multiple popular press articles.<sup>38</sup>

Research conducted by Lynch, Mulvaney and colleagues<sup>39</sup> suggests that patients who have had SGB reported immediate improvements in biologicallybased hyperarousal symptoms such as irritability or angry outbursts, difficulty concentrating, and sleep disturbance. Months after receiving SGB, patients continued to report sustained relief from symptoms like irritability and difficulty concentrating as well as improvements in symptoms like feeling distant or cut off and feeling emotionally numb.

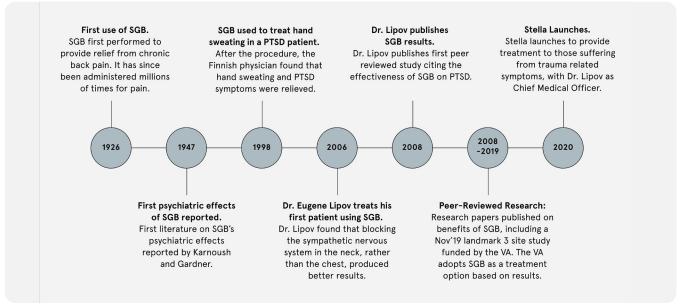
Corporate leaders, executives, and individuals in chronically stressful occupations, such as air traffic controllers, may also present with the target symptoms. Patients who may benefit from SGB do not always meet criteria for a diagnosis of PTSD, but they have the hyperarousal symptoms that SGB has been shown to target. For example, combat veterans may show many of the hyperarousal symptoms following a deployment without meeting full criteria for PTSD. Corporate leaders, executives, and individuals in chronically stressful occupations, such as air traffic controllers, may also present with the target symptoms. Anecdotal reports are now emerging of elite athletes who are using SGB to address nervous system over-activation, as related symptoms can be a barrier to optimal performance.

The accumulation of hyperarousal symptoms may in fact be a "normative occupational hazard" of certain professions, including police officers, firefighters, EMTs, dispatchers, combat flight nurses, and medical professionals who treat COVID-positive patients. SGB can offer relief for the symptoms associated with chronic high stress or trauma exposure that is a routine part of these professions. Dr. Eugene Lipov is widely regarded to have made the initial discovery that SGB has promise for the treatment of trauma symptoms. For well over a decade, since he published a case study that proactively explored the hypothesis that SGB would alleviate trauma symptoms in 2008,<sup>40</sup> Dr. Lipov and other key SGB pioneers have treated thousands of patients and have continually refined and further advanced the use of SGB for trauma.

Yet, despite the fact that thousands of patients have found relief from trauma symptoms with SGB, relatively few trauma sufferers are aware of it. A major reason for this is that research and practice have mainly occurred within active-duty military contexts. Other SGB pioneers have included physicians who have also spent much of their career within active-duty settings, including Drs. Sean Mulvaney, Jim Lynch, Brian McLean, Ali Turabi, and other teams of physicians at Ft. Bragg, Walter Reed Medical Center, the US military base in Landstuhl, Germany, and Madigan Army Base in Ft. Lewis Washington.

Physicians operating within the Department of Veterans Affairs have also helped to advance the practice of SGB, including Dr. Fernandes from the VA Northern California Health Care System, and a group of providers who are leading efforts at the Long Beach VA. Due to the efforts of these pioneering physicians, SGB is considered a "go-to" intervention within several units within special forces and within select military hospitals and a few, select VA hospitals.

In the final analysis, the civilian/military divide has led to a nearly total lack of awareness of this procedure within the civilian population. Few Americans have direct contact in their entire lifespan with any active duty or prior service members who have been part of the fabled military units based at Ft. Bragg, including 82nd Airborne, XVIII Airborne Corps, FORSCOM, USARC, 18th Aviation Brigade, 4th Medical Command and the US Army Special Operations Command – where SGB has been routinely deployed in support of active-duty service members.



Over the course of the last two decades, SGB has been the subject of significant clinical research to effectively address symptoms of PTSD and emotional trauma.

An excellent and comprehensive review out of Johns Hopkins authored by Summers and Nevin provides a detailed analysis of the evolution of SGB-related research through 2016.<sup>41</sup> The following provides a summary and overview of key studies in the field through 2021, the year of publication of this white paper, to include studies referenced in Summers' and Nevins' comprehensive review.

During the 1940s and 1950s, research was published on 3 cases that prospectively hypothesized a positive effect of SGB for depression.<sup>42</sup> While results were promising, following the publication of these studies, SGB was not adopted to treat depressive symptoms.

After a long absence of further research on SGB for psychiatric conditions, the next study identified in the literature was the 1990 study by Lebovits and colleagues.<sup>43</sup> This case involved treatment for pain in a patient suffering from physical and emotional distress following a gunshot wound. In this case report, SGB is linked to the patient's increased willingness and comfort with seeing her psychologist for co-treatment. However, no direct results of SGB on emotional trauma or other psychiatric symptoms were reported.

Following the Lebovits study, 8 years elapsed before another study specifically mentioned SGB in connection with psychiatric distress. In 1998, a study was published by Teleranta and colleagues.<sup>44</sup> This study explored whether endoscopic transthoracic sympathectomy (ETS), more invasive but similar in function to Stellate Ganglion Block, could address symptoms of social phobia. Results were promising – patients who received ETS had statistically significant decreases in both physical and psychological symptoms.

"...the patient was attacked during a robbery and was scheduled for admission to a psychiatric ward. He received an SGB and no longer needed to be admitted for inpatient care due to the immediate change in his symptoms following SGB. This case first showed me the potential for SGB to treat trauma." The Teleranta study was an important advancement because it led to the first prospective case study exploring whether SGB might relieve symptoms of PTSD. Based on the work of Karnoush, Teleranta and others, Lipov ultimately hypothesized that neurological connections running between the sympathetic ganglion and the brain structures become hyperactivated following trauma exposure, that this leads to increases in nerve growth factor and norepinephrine levels, which are associated with increased trauma symptom activation, and that injection of an anesthetic medication into the Stellate Ganglion nerve bundle might alleviate trauma symptoms.<sup>45</sup>

Lipov initially tested this theory in his first case study on SGB, a 48-year-old armed robbery victim who had not found relief from conventional treatments. As Lipov has explained (direct quote via personal communication), "...the patient was attacked during a robbery and was scheduled for admission to a psychiatric ward. He received an SGB and no longer needed to be admitted for inpatient care due to the immediate change in his symptoms following SGB. This case first showed me the potential for SGB to treat trauma."

DR. EUGENE LIPOV

"A vital element of treating chronic PTSD is educating patients that PTSD is a medical condition where the sympathetic nervous system has become chronically activated. Expecting them to "just get over it" is like expecting a patient to "just get over" a femur fracture or cancer."

SEAN MULVANEY, M.D.

Other pioneering physicians began to publish promising results, showing an association between SGB and relief of trauma symptoms. Mulvaney and colleagues initiated an active program of practice and research applying SGB to the treatment of military veterans with PTSD. Mulvaney and colleagues published the first large case series, showing positive results of SGB for PTSD within a sample of 166 active-duty military patients who received a follow-up assessment 6 months after the intervention.<sup>46</sup> As Mulvaney explained (direct quote via personal communication), "In this case series of 166 patients, SGB was shown to be safe and effective, with more than 70% of patients having clinically significant relief from trauma symptoms for up to 3 months after the procedure."

In the same year, Navaie and colleagues published the first systematic review of case reports and case series, showing convergence among investigators as to the observed treatment outcomes of using SGB for PTSD.<sup>47</sup> In this study, 75% of patients showed a clinically meaningful improvement in trauma symptoms. Moreover, there appeared to be a dose-response relationship as PTSD symptoms improved by about 50% for patients who received one SGB, and 69% for those who received multiple SGBs.

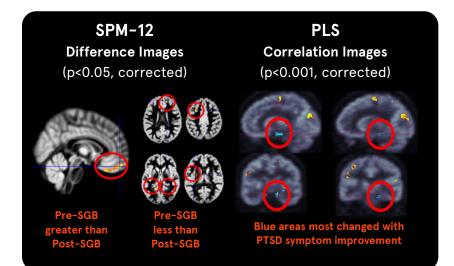
Shortly thereafter, during the following year, Hanling and colleagues presented a poster displaying results of a small sample randomized clinical trial ("RCT") of military service members. The study had randomized a total of 42 individuals into two conditions – 27 received SGB and 15 received a sham injection. Results showed improvements in PTSD within both conditions, with no statistically significant differences between groups.<sup>48</sup>

The Hanling study has been roundly criticized in the literature for methodological flaws. For instance, as Summers and Nevins explain in their 2016 review of the literature, "in the RCT, many of the subjects with PTSD were transitioning out of military service and undergoing medical board review to determine the extent of their disability and their subsequent level of monetary compensation for PTSD symptoms. It appears highly plausible that subjects in such a setting might be inclined to underreport any beneficial effects from treatment out of concern that documented improvements during the study might reduce monetary compensation for their disability." In addition, Summers and Nevins point out that "the use of an inappropriate placebo, and a randomization ratio that overweighted the placebo group" are additional "possible reasons for a lack of positive results in this small trial."<sup>49</sup>

Meanwhile during the same year, Dr. Brian McLean published a study with a sizeable sample of 250 active duty servicemembers that further established SGB as a safe procedure with no immediate or long-term side effects.<sup>50</sup> Noteworthy within these results was the data captured anonymously from those who had received SGB for trauma symptoms: 100% were satisfied with the procedure and would recommend it to a friend.

More studies emerged to explore increasingly sophisticated research questions beyond the initial inquiries designed to answer these questions: "Is SGB safe and does it alleviate PTSD symptoms?"

For instance, Mulvaney and colleagues showed that within a sample of patients drawn from the Special Forces community, SGB actually improves reaction time, motor quickness, vigilance, memory, and concentration.<sup>51</sup> This study made a critical contribution to increasing the acceptability of SGB within certain populations, such as military service members, police officers, and other first responders, whose occupational performance is based on these factors.



Investigators within the Long Beach VA Healthcare System have also played a role in innovating and socializing the use of SGB for PTSD within the VA healthcare system. Alkire and colleagues (2015) showed evidence that trauma exposure causes visible changes in the brain that can be captured on a brain scan. As Alkire related (direct quote via personal communication), "This early result - based on a small sample - suggests that the changes in symptoms were related to the changes in amygdala/ hippocampal functioning induced by the SGB. A bigger study may help us learn what circuits and targets in the brain are important for PTSD and its response to SGB."52

Lynch and colleagues (2016) then explored which specific trauma symptoms are targeted with SGB and discovered that positive effects are seen by reductions in the hyperarousal cluster of trauma symptoms. As Lynch explains (direct quote via personal communication), "in the first week following the block, hyperarousal symptoms were most affected such as irritability, angry outbursts, difficulty concentrating, and trouble falling or staying asleep. Two to four months later, greatest improvements were seen in the following: feeling distant or cut off, feeling emotionally numb, irritability or angry outbursts, and difficulty concentrating."<sup>55</sup>

"PTSD is hard to treat, largely because effective treatments come with some difficult side effects and challenges. SGB represents a new and better-tolerated treatment option for those suffering from PTSD." This focus on specific symptoms was an important advancement as it opened up the possibility of treating an identified form of suffering, characterized by a set of clear symptoms, rather than limiting the focus of treatment to those with a particular diagnosis. In a later publication, Lynch explored how Stellate Ganglion Block is a "precision medicine treatment" which involves a "focus on specific symptoms rather than a heterogenous diagnosis" that has "over 636,000 possible combinations of symptoms."<sup>54</sup>

The RCT that many were awaiting was published in JAMA Psychiatry in 2019. This involved a much larger randomized clinical trial at 3 military hospitals. The study's principal investigator, Kristine Rae Olmsted, summarized these findings in this way: "PTSD is hard to treat, largely because effective treatments come with some difficult side effects and challenges. SGB represents a new and better-tolerated treatment option for those suffering from PTSD" (direct quote, personal communication).<sup>55</sup>

KRISTINE RAE OLMSTED

The U.S. Army Medical Research and Development Command (USAMRDC), a Department of Defense (DoD) initiative, has awarded RTI International another \$4.5 million to expand its research on SGB for trauma symptoms. This funding will be used for two purposes - to conduct secondary analyses of data from the original RCT and to run a yearlong cohort study following service members and veterans treated at five military hospitals. The cohort study will explore the number of injections patients typically require for lasting relief from PTSD symptoms, and the durability of positive effects, as well as any potential risks of multiple treatments.56

Following the RCT, studies have looked at improvements in procedure and technique, the longevity of SGB, the acceptability of SGB as part of a treatment plan for behavioral health clinicians, and the application of SGB regardless of the nature of trauma sustained. Mulvaney et al (2021) showed that a left-sided injection given to those who did not respond to the traditional right-sided injection led to positive treatment outcomes for some among the follow-up treatment group.<sup>57</sup> Another study showed that the traditional single block given on the right side might be enhanced by a second injection placed higher on the neck.58

Lynch's paper on SGB as a precision medicine treatment for posttraumatic stress argued that SGB is not best used as a standalone treatment, but rather as an adjunct with a precise purpose to complement traumafocused psychotherapy.<sup>59</sup>

And in 2021, Lynch et al surveyed 23 behavioral health providers, including psychiatrists, psychologists, and mental health social workers, who had all observed the impact of using SGB in combination with psychotherapy. The vast majority (95%) of those surveyed would recommend SGB to a colleague as a useful tool for the treatment of trauma-related disorders. Fully 100% of respondents characterized SGB as 'Very Beneficial' or 'Somewhat Beneficial', and none of those surveyed characterized SGB as 'Not Helpful' or 'Harmful'.60

# would recommend SGB to a colleague

### **Exploratory Research on the Largest Sample to Date**

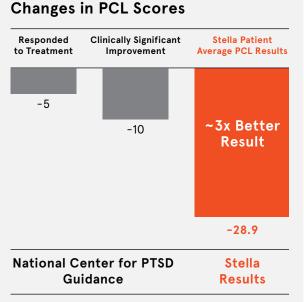
To explore whether SGB has positive outcomes across multiple types of trauma, Stella has analyzed data within the largest sample to date: a retrospective study of 327 patients treated between 2016-2020. Because Stella operates in the civilian sector, the sample of treated patients represents the largest group of females studied to date and represents individuals with a wide variety of traumatic exposures.<sup>61</sup>

Results of this study showed clinically significant outcomes in over 80% of those treated within a single clinic visit. This is defined as a decrease in the PCL of at least 10 points, a standard of treatment success that is set by the National Center for PTSD. Moreover, the average change in symptom severity scores was a drop

95%

of mental health care providers

Lynch, et al 2021



Sample of 327 patients treated between December 2016 and February 2020. Data has been reviewed by an IRB and submitted to a peer reviewed journal for publication (acceptance pending). of 28.59 points on the PCL for males, and 29.2 for females, respectively. Functionally, these decreases translate to taking someone with very high severity to a very low symptom severity level. In the sample, military males and females had a greater decrease in symptom severity scores than civilian males and females, respectively.

Further, these gains held across several types of trauma including distal traumatic exposures such as childhood emotional abuse and childhood sexual abuse. In a few select trauma categories like "bullying/hazing" and "domestic violence," the limited number of individuals in that analysis group created insufficient statistical significance to determine effects, but in the vast majority of trauma types, ranging from sexual assault, to combat trauma, car/other accidents, head injury, and health issues, SGB showed a positive treatment outcome. The fact that SGB was associated with positive outcomes across multiple trauma types, and for traumas both old and new, is further evidence of the biological injury model of trauma and the potential application of SGB regardless of the source of trauma.

#### Success Outcomes by Trauma Symptoms

Depression / Anxiety 82%	Panic / Paranoia	Tremors / Shakyness
Agitation / Nervousness	Suicidal Thoughts / Attempts	Frequent Headaches
Issues concentrating / remembering	Weakenss / Dizziness / Vertigo	Alcohol / Drug Abuse
Mood swings		

#### Safety and Efficacy of SGB

One of the greatest barriers to understanding the potential value of this procedure is widespread misunderstanding about the concepts of "FDA approval" and "off-label use." Legally, those who provide SGB for trauma symptoms are required to state that SGB is not FDA-approved for use with trauma symptoms. The phrase "not FDA-approved" raises the specter of an "unsafe" or "dangerous"

procedure or something that is "untested." Due to its current FDA approval status, SGB for trauma is not reimbursed by medicare or private insurance. However, SGB is often covered by healthcare rebates in Australia.

The medications used are FDA-approved anesthetics that are used every day for countless women to provide epidurals during childbirth as well as many other applications in the pain management field. As mentioned, the SGB intervention has been used to treat pain conditions for nearly a century.

For the past decade, SGB has been applied to symptoms of trauma in the same way that aspirin is used to reduce risk of heart attack. Aspirin is also "not FDA-approved" for use in this way - like SGB, it was also primarily developed to treat pain, but has shown clear promise in many documented medical cases for reducing cardiac risk factors.

In comparison to other invasive interventions, the risk of negative outcomes is low. In a 1992 survey of 45,000 individuals, the incidence of severe complications was 1.7 per 1000 procedures, with no fatalities reported.<sup>62</sup> Additional safety precautions have been developed since this study. To ensure correct placement of the injection, medically qualified providers use ultrasound, fluoroscopy, or computed tomography to help visualize the injection area.

Referenced briefly in the previous literature review is a key study published in 2015, by Dr. Brian McLean, an active-duty military physician operating out of Tripler Army Medical Center. This study reviewed outcomes of 250 stellate ganglion blocks over an 18-month period to detect any potential complications or unanticipated side effects. Anonymous surveys were also collected to evaluate patients' comfort and satisfaction with the procedure. In this sample, there were neither immediate nor delayed complications of any kind. Moreover, 100% of those surveyed were satisfied with the process and with the procedure, 100% said they would recommend the procedure to a friend, and 95% stated that they would be willing to undergo as many repeat procedures as necessary based on little discomfort and tolerable side effects.<sup>63</sup>

SGB is a 'safe' and 'ethical' treatment option for those with trauma.

DEPARTMENT OF VETERANS AFFAIRS CENTER FOR COMPASSIONATE INNOVATION Similarly, outcomes of a recent multi-site, randomized clinical trial, published in JAMA Psychiatry, are promising. Researchers describe Stellate Ganglion Block as a "safe, routine procedure" and state that "results are congruent with case reports and case series that have reported improvements in PTSD symptoms after SGB." SGB is now a "go-to" intervention within several military medical facilities and is described by the Center for Compassionate Innovation within the Department of Veterans Affairs as a "safe and ethical" treatment option for those with trauma.<sup>64</sup>

In the literature, across articles documenting case series outcomes, Stellate Ganglion Block has a success rate ranging from 70-75 percent on average.<sup>65</sup>

As described above, in a retrospective cohort analysis of 327 patients treated from 2016-2020, over 80% of patients experienced a 10-point drop in the PCL-4 (the threshold for a clinically meaningful response as defined by the National Center for PTSD).

#### A New Model for Treatment:

Realizing the potential of the Bio-Psycho-Social Model of Care

Despite its promise, SGB is not best applied as a standalone treatment. Despite its promise, SGB is not best applied as a standalone treatment. When SGB is used in combination with psychotherapy and other mindbody wellness practices, its full power is unleashed. Recall that SGB was discovered in the context of an understanding that PTS injury is largely a biological condition that is maintained by changes in thinking and behavior. Addressing the underlying thinking and behavior that maintain the trauma response through therapies designed for this purpose will maximize the possibility of achieving long-term treatment gains.

SGB and therapy have a reciprocal enhancement effect that is bi-directional in nature. While some systems of care provide for SGB as an interventional procedure to be offered only when other treatments have not worked, this shows a fundamental misunderstanding of how SGB works in combination with therapy. As one patient put it, SGB is the "primer" before the "paint" of psychotherapy and other wellness programs.

To understand how this works, it's key to observe how a chronically overactivated "fight or flight" system impedes engagement in care and creates an obstacle to positive therapy outcomes. In the psychology performance literature, the relationship between stress and performance is described by something called the "Yerkes-Dodson Law of Arousal."<sup>66</sup>

To summarize this literature, some stress can help us perform. However, a high level of stress will often impair our performance. If a task is relatively simple, then a high level of arousal/stress may not be a problem. In other words, many simple tasks can be performed at a high standard after a few shots of espresso. But for complex tasks that demand decision-making, working memory, and multitasking, too much arousal (stress) often impairs our performance.

Think of the example of a professional baseball pitcher who is a "clutch" player he or she is brought into the game at a "make or break" moment for the team. An effective clutch player manages stress in a way that most of us could not. With the pressure of the game's outcome at stake, he or she is able to find their ideal zone of performance by keeping stress at an optimal level. If that player fails to manage his or her level of stress, he or she may "choke" and fail to perform.

The new model of care that combines SGB and other trauma-focused treatments is an application of the Yerkes-Dodson Law of Arousal to psychotherapy. A common adage is that "psychotherapy is work." Therapy is emotionally and mentally exhausting because it involves highly complex mental work. During a therapeutic session, we move through time in our minds - to draw from memories of the past, and to feel experiences that may be painful in the present. It is equally important to envision the future - to get a specific picture of where we want our lives to change.

Therapy often requires that we engage in thinking and feeling that is both "in the moment" and "meta-cognitive." Meta-cognition involves zooming out and hovering over a feeling, thought, or interaction so that we can analyze it from

"When SGB is used in combination with psychotherapy and other mind-body wellness practices, its full power is unleashed."

**DR. SHAUNA SPRINGER** 

a different perspective. In addition, therapy requires acute sensitivity to what is happening inside of our bodies and minds in the moment, a form of deep mindfulness that takes concentration. All of these therapeutic efforts require complex mental work.

At the same time, trauma has an impact on our bodies and minds that can impair our ability to fully engage in therapy. Consistent with this, research has shown that hyperarousal symptoms are an independent predictor of nonresponse to standard PTSD treatment.<sup>67</sup> To draw out a specific example, one of the most common symptoms of trauma is difficulties concentrating. Trauma fragments our ability to concentrate, making the work of maintaining focused attention very challenging.

Based on this, we can see how reducing a person's level of anxiety could change everything about the experience of therapy. To return to the previous analogy that SGB is the "primer" before the "paint," once an individual is restored to a feeling of calm, they are primed to receive new insights, learn new ways to understand their trauma, and integrate new behaviors to achieve long-lasting recovery. The work of skilled psychologists, social workers, mental health counselors, wellness coaches, and mind-body practitioners is critical to this process.



The new model for care involves the fusion of biological, psychological, and mind-body practices as the key to sustaining long-term recovery. In this new model of care, the sequencing of these

elements matters. To provide an analogy, SGB would be akin to getting a knee replacement and then the psychotherapy would be similar to the physical therapy needed to rebuild the muscles and repair the tissues in order to set up longlasting positive post-surgical outcomes.

In this way, Stellate Ganglion Block, used in combination with high quality mental health support, brings new promise as a safe, efficacious, accelerated path to recovery.

#### **Building Out the Full Continuum of Care**

As the fastest growing and largest provider of Stellate Ganglion Block procedures, Stella is fully committed to this new model of care: the fusion of SGB with other healing modalities. To realize the potential for the full continuum of care that brings long-lasting positive outcomes, Stella has invested in a training certification series that helps care partners understand how SGB is used to prime and accelerate positive outcomes for other treatments. This certification series is offered to providers across the country, to help educate them about Stellate Ganglion Block and provide guidance on how to best support any patients who elect to pursue SGB prior to or in addition to other treatments.

Stella has also begun building out a national network of providers who are wellinformed in how combining SGB and the therapy they offer can benefit their patients. This includes partnerships with organizations that offer high-quality, culturally competent programming that can be paired with Stellate Ganglion Block.

#### Strategic Advantages of SGB

An injury can be healed, and SGB works as a precision medicine treatment. The availability of SGB as a treatment for symptoms related to trauma and chronic stress overload brings many strategic advantages. First, SGB is aligned with an "injury" rather than a "disorder" frame of thinking. The injury model eliminates a common barrier to care – the stigma that is related to seeking help for a "mental health disorder." An injury can be healed, and SGB works as a precision medicine treatment. When an SGB is placed correctly by a skilled provider, there are no documented long-term side effects.

A properly placed injection causes a temporary effect called "Horner's Syndrome", <sup>68</sup> which has been consistently documented in the medical literature, whether SGB is used to treat pain or emotional trauma symptoms. Horner's Syndrome involves ptosis (a visibly droopy eyelid), miosis (a constricted pupil), and scleral injection (redness in the eye), all on the side where the injection was placed. Just as numbness from novocaine injected during a dental procedure resolves in a matter of hours, Horner's Syndrome also resolves on its own within 24 hours of the SGB procedure. In fact, among providers who perform SGB, Horner's Syndrome is thought to be desirable as it indicates and confirms the accurate placement of the anesthetic medication into the Stellate Ganglion nerve bundle.

In addition, the medication that is injected is not a psychoactive medication, but rather a widely used anesthetic medication, further reducing stigma related to mental health concerns. In fact, the success of SGB, based on the use of the same medication that is used for epidurals during childbirth, is an argument in favor of the biological impact of trauma and stress, and the healing that is possible to achieve within this framework of understanding.

In addition, because the medication is non-psychoactive, there is no risk of a "positive" drug test which is particularly important to individuals in certain careers and occupations. The medication does not remain in the body over time. The use of a non-psychoactive medication is also critical because it can bring relief without the fear associated with loss of control. In recent years, innovation

#### **Possible Advantages of SGB**

No documented long-term side effects No risk of positive "illicit" drug test Rapid relief No drop out from care Cost savings due to efficiency
Rapid relief No drop out from care
No drop out from care
•
Cost savings due to efficiency
/
More access to care
Accelerates the outcomes of psychotherapy
Increases hopefulness
Patients don't have to share their trauma story in detail

#### **Possible Limitations**

- 10%-20% don't respond
- Potential complications (though very safe when performed by skilled physician)
- Not a "miracle cure"

has led to important discoveries around the use of psychedelic medications to treat post-traumatic stress symptoms. There appear to be some very promising treatments on the horizon with this line of work. However, one of the biggest barriers will be fear of loss of control. Patients who have suffered trauma often develop a default protective mode. Asking someone who has been traumatized to yield to the journey of a psychedelic medication will be a bridge too far for many patients. The fear of losing control is often too great as a barrier to care. Conversely, SGB offers a pathway to treat these patients while they are fully aware throughout the procedure, and without the use of psychoactive medication.

The rapid onset of relief is another substantial advantage of SGB. A successful procedure often brings immediate benefit in the minutes or hours directly following the procedure. This also allows providers to efficiently assess whether a follow-up procedure may be indicated on the opposite side, if the first injection did not bring substantial relief of trauma symptoms. Because it works so quickly, treatment drop out is essentially a non-factor – most patients find relief from a single procedure that takes about 15 minutes.

The speed of efficacy becomes critical in cases where patients struggle with hopelessness. Trauma can be associated with identity changes such as a feeling of "being broken" or that PTSD is a "life sentence." A treatment that often works so quickly is a powerful antidote to the feeling that one has been irreversibly altered in a negative way. A common observation among treated patients is what this writer (Dr. Springer) refers to as the "burst of hope effect." Specifically, because a successful SGB can greatly reduce traumatic stress symptoms so quickly, patients often experience a burst of hope that can propel them forward into other treatments and healing modalities.

In addition, the efficiency of SGB directly translates to substantial cost savings over treatments that require weeks, months, or even years of care. The average cost of a single SGB treatment runs between \$2000-3000, which compares favorably to other more protracted or costly treatments. A further benefit of SGB's efficiency is that many more people will have access to care that brings them rapid relief. A skilled SGB provider can treat up to 15 people within a single day at a clinic. Stella's rapid expansion across the United States and beyond also creates new access to this innovative treatment option.

The final advantage of SGB is that it operates as an accelerant for a wide variety of paired healing modalities and treatments. SGB opens up a window of opportunity for people to benefit from treatment without the barrier of fighting through symptoms like difficulties concentrating and overwhelming surges of anxiety. When calm is restored in the body, patients can be fully present in therapy. They are ready to receive new insights, learn new ways of thinking about their challenges, and can better focus on changing any unhelpful patterns of behavior that are associated with trauma or chronic stress.

In addition, when "chronic threat response" is addressed, patients are often able to experience a wider range of warm, positive, loving feelings towards

	Stella SGB The Dual Sympathetic Reset	Traditional SGB
Board Certified Doctor	$\odot$	Varies
rained by SGB for PTSD Expert	$\oslash$	$\otimes$
linical Compliance	National Safety and Quality Assurance Varies	
jection Level(s) Dual-Injection at C6 and C4 (or C3) Single injection		Single injection at C6
Right sided;           Side of the Neck         For right side non-responders, same protocol on left side         Right sided on		Right sided only
Physician Experience Level	Level 100+ SGBs performed Va	
Sedation Options	Twilight sedation or local anesthesia	Varies
Multiple Follow-Ups		$\otimes$
Psychotherapy Referrals	erapy Referrals	
tional Presence		$\otimes$
Fravel Assistance	$\bigotimes$	
Financing Plans	$\bigcirc$	$\otimes$

others in their lives. This change is not because of a psychoactive medication, but rather because of the removal of debilitating symptoms like sudden surges of irritability, the distraction of hypervigilance, and a continual feeling of being under threat. SGB may show utility when combined with psychedelic medications for individuals who want to go deeper in exploring self-compassion as an adaptive response to trauma. SGB may give these individuals a head start and a way to enter such programs in a calm and composed frame of mind.

Finally, another unique benefit of SGB is that patients do not need to share their trauma story in detail before they experience relief from some of their most acute symptoms of trauma. SGB gives patients an option to receive relief through a biological intervention that can make other treatments much more compassionate. When patients feel calm again in their own bodies, they are often able to view the experiences they've had through a different lens. SGB can bring immediate relief, and many can achieve long-lasting healing with the support of skilled therapy providers and other paired treatment modalities like mindfulness, wellness coaching, and yoga practice.

#### **Common Sources of Misunderstanding**

While SGB is not a new treatment, it is not a treatment many patients and providers are familiar with as of this writing. As such, there are a few common misperceptions and concerns that should be addressed in support of an accurate understanding.

One common misperception is that SGB may cause someone to "lose their edge." Those in certain professions, as military service members and first responders, need to retain their ability to react quickly and decisively in response to a real threat.

To test this concern, researchers within the Special Forces community

The results showed that successful SGB procedures actually increased the performance of military operators in the areas of sensorimotor speed, visual learning and spatial working memory, working memory, and vigilant attention.

MULVANEY, ET AL, 2015

conducted a study to explore the association between SGB and performance. The results showed that successful SGB procedures actually increased the performance of military operators in the areas of sensorimotor speed, visual learning, working memory, and vigilant attention.<sup>69</sup> This makes sense because when we treat symptoms like difficulties concentrating and disrupted sleep, performance would be expected to improve. In fact, within certain special forces units, SGB has become a go-to treatment for symptoms of combat trauma exposure.

Another common misperception is that because the medication does not remain in the body, the positive effect of SGB will always be short lived. The medication acts by restoring the system to a sense of calm and control. In some cases, the positive effect of Stellate Ganglion Block injections can last for a year to several years, depending on the individual. There are many factors in determining how long a positive result may last.

The most significant factor may be this: what happens to change the underlying thinking and behavioral patterns that maintain a trauma response after SGB gives an individual the window of opportunity to address these things. Posttraumatic stress may be an injury, but the impact of trauma is maintained by changes in how we think and behave. If we do not learn new ways to think about our trauma and to navigate the world around us differently, over time, we are likely to experience a slow fade of the positive benefits of SGB. Sometimes this can occur over many months, and at other times, this may take years.

This is why SGB is best paired with other treatments. It is the fusion of biological and psychological interventions that holds the greatest promise for delivering long-lasting positive results. This is the new model of care, and this is why Stella, the nation's largest provider of SGB, actively seeks to refer patients to trusted therapists.

Finally, a third common misperception is that SGB will require a prolonged period of recovery following the procedure. In reality, recovery time is minimal – most patients report that they feel rested and able to return to normal activities 24 hours after their procedure. This short duration of downtime can be helpful to those in occupations that do not afford them to take long breaks. For instance,

Timeline of	Care if Travelir	Ig	
Day 1	Day 2	Day 3	Day 4
Arrive in town of Stella location	Receive Treatment	Fly home	Possible to resume normal work activities

Stella has treated frontline healthcare workers who are fighting to save those infected with COVID.

Let's take the example of a nurse working in New York who is treated at our Stella facility in Chicago. In most instances, it's possible for this individual to arrive in Chicago on day 1, receive treatment on Day

\*It is encouraged to stay an extra day in case a second injection is needed.

2, fly home on Day 3, and resume normal work activities on Day 4. For patients who are coming in from out of town, however, we often encourage them to stay one additional day, on the off chance that an injection is needed on the opposite side of the neck following the first injection. In any case, after an SGB procedure, the downtime is about 24 hours. In addition to service members and first responders, Stella has also treated corporate executives and leaders who value access to a treatment with a very brief downtime that is administered in a private, confidential way.

Any given intervention has limitations and there is no single treatment that works for every individual. There are between 10-20% of patients for whom SGB does not seem to be effective. As SGB innovators continue to refine their methods, this percentage will improve but there is always likely to be some portion of patients who will not benefit from the treatment.

Related to this, it is not yet clear whether right or left sided SGB, or both in succession, will yield the best results for a given patient. The convention has been to treat the right side, and then to offer a left-sided injection if the right fails to bring relief of symptoms.

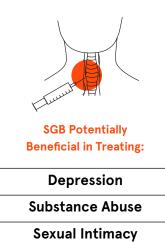
To a qualified, well-trained provider, SGB is a minimally invasive procedure. For many pain physicians, SGB is offered on a fairly routine basis. There is always a risk with any intervention that is performed by an unskilled or poorly trained provider. While the risk of adverse outcomes is very low with SGB, there is always the possibility of a serious side effect like a pneumothorax or seizure if the injection is not performed by a skilled provider. A good analogy to illustrate this is that if a pilot who is qualified to fly an F-18 were asked to complete a simple takeoff and landing, this would be considered an easy objective.

However, if an unqualified or unskilled pilot were asked to do the same, this would heighten the risk of damage to the airplane. For this reason, it is absolutely critical that those who seek this procedure ensure that they are receiving it from a qualified, well-trained provider who is using the most up-to-date methods for visualizing the injection area.

A further limitation is that SGB has been considered by some to be a "miracle cure." This mentality promotes the belief that trauma recovery can be a passive process. In other words, some individuals may be tempted to believe that lying still for a few moments to receive an injection is all that is required to gain recovery after trauma exposure. This is a limitation because this may promote short-lived gains, rather than long-lasting recovery.

Addressing the underlying thinking and behavior, and more complex factors like the identity changes that are often associated with trauma, are a critical part of recovery. While we do not have data to show how long SGB lasts, it is important for those who receive it to understand that recovery may require addressing psychological shifts and patterns of behavior. As a psychologist who worked with hundreds of patients in the Department of Veterans Affairs earlier in my career, it was clear that those who lived as though they were still at war, stayed at war, in their minds and bodies.

#### **Future Directions to Explore**



Secondary PTSD

Stellate Ganglion Block may have other potentially helpful applications. For instance, the first documented psychiatric case study, published in 1947,<sup>70</sup> tested SGB as an intervention for depression. It showed a potential response in this initial case study but this line of inquiry was not pursued any further. This may be because pharmaceutical agents to treat depression, like Prozac and other medications developed thereafter, came to the fore as potentially promising.

Further study of the potential effect of SGB on depression may warrant further investigation. To this point, based on the clinical observations of this writer (Dr. Springer), in many cases, depression and anxiety are meaningfully linked. While diagnosticians often separate these into two separate categories, time and further research may reveal this theorized association between anxiety and depression: when an individual has faced chronic anxiety over a sustained duration of time, on a macro-level, the body can "crash" into a depressive state.

Conditions like a global pandemic, continuous political discord, race- and gender-related oppression, and record-breaking natural disasters are just the kind of "perfect storm" that may lead to chronic stress induced fatigue and depression for many across the globe. These individuals may not show up on the radar in terms of traditional care settings if they are not victims of any identifiable traumatic event. They may not meet criteria for PTSD, or major depression, but may present with a chronic dysthymic state that was preceded and catalyzed by a prolonged period of "chronic threat response."

A second potential indication, though anecdotal at this time, is that SGB may support recovery from substance abuse, including nicotine, alcohol, and/or opiate dependence or abuse. Individuals often use substances to help regulate their inner state of being. For instance, habitual cigarette smokers and heavy drinkers often engage in this behavior to address uncomfortable feelings of anxiety, or to self-medicate chronic sleep problems. Among the pool of patients we've treated, several have commented that they are able to finally get traction in quitting smoking or stopping a pattern of abusing alcohol once their trauma symptoms were successfully addressed by SGB.

A third area for potential exploration is how SGB may support individuals who have sustained traumatic brain injuries (TBI). Stella has treated approximately 2000 individuals since its launch in 2020, many of whom are military veterans with comorbid diagnoses of PTSD and TBI. SGB has been effective in alleviating hyper-reactivity in the vast majority of these individuals. There are a few lines of exploration that are of particular interest. For example, does offering SGB in the immediate wake of a head injury or concussion decrease the impact of the injury to the brain? In other words, does addressing nervous system dysregulation alter the onset or course of the disease?

Within the same area of focus, a second line of exploration is to see whether SGB can functionally disentangle PTS symptoms from TBI symptoms. One of the persistent challenges of neuropsychological assessment is to discriminate between the impact of psychological trauma and concussive injuries for patients with dual exposures. If SGB can restore a sense of calm, and decrease impulsive over-reactivity and difficulties concentrating, two of the hallmark symptoms of TBI, this may help providers discern the relative contribution of TBI vs. PTS to a constellation of symptoms.

A fourth intriguing line of inquiry would be to explore the potential association between SGB and relationship improvements, to include an increase in satisfaction with sexual intimacy. The sexual response is primarily a relaxation and bonding response. Chronic sleep disruption, and high levels of (the wrong kind) of hyperarousal symptoms, like surges in anxiety or irritability, can impede sexual performance and compromise our ability to meaningfully connect in our close relationships. By calming the body, patients may find that sexual and intimate connection improves.

Finally, a fifth promising area for further exploration is to explore how SGB may improve relationships and quality of life for couples through co-treatment of PTS in both partners in the relationship. Regardless of which partner in a relationship was first diagnosed with PTSD, the same set of challenges are often reflected in others they live with. A spouse who is jerked awake at night repeatedly by his or her partner's vivid nightmares will often develop chronic sleep difficulties. Surges of anxiety or panic attacks in one member of a family can limit activities for the entire family. Hypervigilance can be transmitted (or taught) to others in the family. Surges of anger or irritability can lead to spouses exhibiting "chronic threat response" as they find themselves "walking on eggshells" over weeks, months, or many years.

Stella has partnered with organizations that treat both military servicemembers and their partners together, and we have started to realize the potential for co-treatment of primary and secondary trauma symptoms within a given couple. Partners in a relationship can be treated on different dates or can go through treatment together, which has been a powerful reset for several couples we've supported in this way.

"I wish I had known about this procedure a long time ago. It could have saved us a lot of heartache, a lot of tears, a lot of arguments, and a lot of sleepless nights. Our lives have changed."

MOLLY ELKINS

To briefly illustrate, one of the couples treated at Stella is Molly and Clarence Elkins. Prior to treatment, they were both experiencing trauma resulting from Clarence's wrongful conviction and imprisonment and the years leading up to his exoneration and release. Clarence suffered from insomnia and nightmares and together they suffered from anxiety. After having the procedure, they report no more nightmares and are living a more normal life per their report. As Molly Elkins put it, "Before the treatment, our life was very difficult. It was sad...it was dark. We couldn't live like normal people live. I wish I had known about this procedure a long time ago. It could have saved us a lot of heartache, a lot of tears, a lot of arguments, and a lot of sleepless nights. Our lives have changed."

Further clinical and theoretical advances and associated research will continue to develop these lines of work and demonstrate the potential for SGB to address these kinds of challenges. Stellate Ganglion Block, as a treatment for trauma symptoms, is still unfamiliar to many who suffer from trauma and to the healers who provide their care. For this reason, Stella has invested heavily in education, focused on both prospective patients and referring providers.

For referring providers, this writer, Dr. Shauna Springer, has presented a year of monthly webinars on a variety of topics related to the use and applicability of SGB as a treatment for trauma. All of these webinars are taped and shared freely at the request of any provider who wants access to them at no charge. In addition, Stella provides a series of filmed training videos, written and narrated by Dr. Springer, with key content from Chief Medical Officer, Dr. Eugene Lipov.

These films have a total runtime of 2 hours and cover a wide variety of topics including:

Debunking 5 Common PTSD Myths Understanding how Anxiety is an Obstacle to Good Treatment Outcomes Personality and SGB Trauma-Informed Care Helping Patients Define Their Core Unit of Support Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	-	
Understanding how Anxiety is an Obstacle to Good Treatment Outcomes Personality and SGB Trauma-Informed Care Helping Patients Define Their Core Unit of Support Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	A New Model for Trauma Care	
Personality and SGB Trauma-Informed Care Helping Patients Define Their Core Unit of Support Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	Debunking 5 Common PTSD Myths	
Trauma-Informed Care Helping Patients Define Their Core Unit of Support Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	Understanding how Anxiety is an Obstacle to Good Treatment Outcomes	
Helping Patients Define Their Core Unit of Support Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	Personality and SGB	
Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy 24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	Trauma-Informed Care	
24 Hours Before SGB: Helping Patients Prepare for Their Procedure Common Patient Questions Working with Non-Responders to SGB	Helping Patients Define Their Core Unit of Support	
Common Patient Questions Working with Non-Responders to SGB	Helping Patients Use Visualization to Enhance Outcomes with SGB + Therapy	
Working with Non-Responders to SGB	24 Hours Before SGB: Helping Patients Prepare for Their Procedure	
	Common Patient Questions	
Normal and Abnormal Responses to SGB	Working with Non-Responders to SGB	
	Normal and Abnormal Responses to SGB	

At the conclusion of the training series, providers are tested with questions about the content and a successful completion of the course requires a score of 80% or higher. Those who pass the course receive basic certification for successful completion of the training and are eligible to receive referrals from Stella. In this way, Stella ensures that care providers in our network have an understanding of the SGB treatment and how to support their patients well during the SGB portion of the healing journey.

Prospective patients have widely varying familiarity with SGB. Some patients have received recommendations to seek treatment from others they trust – friends who have had the treatment, or providers who have worked with patients following SGB. For patients as well, there is a need for education that is attuned to the level of understanding desired by a given individual.

Information about SGB is provided through written thought pieces, radio interviews, television features, film projects, patient-focused webinars, speaking engagements, and videotaped testimonials from patients who have had SGB.

#### **Stella Patient Journey**

Consultation with Patient Care Coordinator to gather mental and physical health information.
Option to speak with a Stella Ambassador.
Medical information reviewed by a provider.
SGB is performed in a single day, typically a 20 minute session.
24 hour follow-up assessment determines need for second SGB;
Consistent check-ins from PCC during the year after treatment support positive outcomes.

Within Stella, patients also have the option of speaking with a Stella Patient Ambassador from a team of volunteers who have had treatment. Stella Ambassadors share the treatment story and answer initial questions about the treatment journey.

Patients can also schedule a free consultation at any time with a Stella Patient Care Coordinator. Patient Care Coordinators within Stella answer a variety of treatment and process related questions and collect information to determine whether a given patient might benefit from SGB. During the initial intake, mental and physical health information is collected and reviewed. Stella collects both standard symptom measures such as the PCL-5 and the GAD-7 and screens for any possible contraindications for having an SGB.

While contraindications are rare, some examples may include a history of Lyme Disease, the use of blood thinning medications (a risk for any invasive procedure) or metal in the neck area where the injection is made (i.e., due to a previous surgery or injury). Patient charts are always reviewed by a qualified medical provider before an SGB procedure is performed. Stella follows suitability criteria developed and managed by Dr. Lipov to assess whether patients qualify medically for the procedure, and he personally reviews higher-risk cases that fall outside of standard operating procedure.

The SGB procedure itself usually occurs over a single day at a clinic, although a smaller portion (typically about 10-20% of those treated) may require a second set of injections provided shortly thereafter. Patients receive follow-up calls on the day after their first procedure to assess whether further treatment is needed. In addition, over a period of 180 days postprocedure, Stella engages in evaluation of symptoms and personal outreach from a member of the Patient Care Team to see how each patient is doing over time. Supporting patients in this way is a core part of offering trauma-informed care.

## Political momentum for making SGB widely available

Based on the potential for SGB to address trauma symptoms within the military and veteran community, legislators in Congress have proposed to make the treatment much more widely available.

Congressman Scott Perry of Pennsylvania has led these efforts through the proposal of the "Treat PTSD Act" (H.R. 1656).<sup>71</sup> Congressman Perry spent 38 years in service in the U.S. Army, ultimately achieving the rank of Brigadier General. Per Congressman Perry's District Director, Jay Ostrich, who also serves in the military, Perry received years of briefings throughout the Global War on Terror and Operation Iraqi Freedom, detailing mental health impacts, including continual suicide losses within the ranks, and noted the need for an effective, efficient strategy to address trauma symptoms.

After watching a feature on SGB on "60 Minutes," and further investigating the outcomes and safety-related data relevant to the treatment, and speaking to veterans who have had SGB, Perry felt compelled to learn all he could about SGB. He discovered that SGB is frequently offered in several major military hospitals and that it is an approved treatment through the Department of Veterans Affairs, but that in the latter case, it is only offered if and when other treatments have failed. Through meetings with leaders in the Department of Veterans Affairs, per Perry's District Director, Jay Ostrich, "Congressman Perry observed that the VA wasn't going to move itself. He realized that it would take an act of Congress to make this available to veterans across the country and felt a moral obligation to act based on his personal history of service."

Ostrich added, "We have more than 80 years of uniformed service within Congressman Perry's team. We are tired of seeing adherence to the status quo continue to take and ruin lives. This is not political for us – it's about doing the right thing for our current and prior service men and women."

Upon this basis, in Spring 2020, Perry and his team proposed the Bill.

#### The TREAT PTSD ACT:

- 1. "Requires the Department of Veterans Affairs (VA) and the Department of Defense (DOD) to furnish stellate ganglion block to certain veterans or members of the Armed Forces (including reserve components) diagnosed with post-traumatic stress disorder (PTSD).
- 2. Authorizes this treatment for any veteran or member of the Armed Forces who (1) is enrolled in the VA health care system or TRICARE program, (2) has been diagnosed with PTSD, and (3) has elected to receive stellate ganglion block after being informed by a physician of the risks and benefits. Such treatment may be furnished at a VA medical center, DoD medical facility, or through a health care provider under the Veterans Community Care Program or TRICARE health insurance program.
- 3. Requires the VA and DOD to update the VA/DOD Clinical Practice Guideline (CPG) for the Management of PTSD to ensure that information about stellate ganglion block is included."<sup>72</sup>

The Treat PTSD Act rapidly received bi-partisan support with the co-sponsorship of Congressman Mark DeSaulnier, a Democrat from the state of California. The bill was reintroduced in March 2021 for the 117th Congress and received bipartisan co-sponsorship within a day of its reintroduction. All of the biggest Veteran Supportive Organizations (VSOs) have now endorsed the Treat PTSD Act. Specifically, the VFW, the American Legion, AMVETS National, and other respected organizations such as the Green Beret Foundation and Mission 22 have also formally endorsed the bill.

The Treat PTSD Act currently has sixteen co-sponsors as of August 2021. In Spring 2020, with a vote of 203-0, all members of the House of Representatives within the state of Pennsylvania, in all parties, voted to support a resolution beseeching all members of congress to pass H.R. 1656, and imploring President Biden to sign the bill. Stellate Ganglion Block has been the subject of some award-winning films. Wounded Heroes<sup>73</sup> was a three-year passion project for director/producer Michael Gier. The film developed from an initial interview with a veteran named Carl, who had served as a medic, and who had struggled with severe symptoms of post-traumatic stress and suicidal ideations. Gier was surprised to learn that Carl had been prescribed 16 different medications, down from 18, to address his symptoms of trauma. Carl explained that the medications didn't do anything to solve the problem; they just dulled the symptoms. The movie traces Gier's journey to find alternative treatments and programs for post-traumatic stress.

Stellate Ganglion Block is one of the many successful alternative treatments featured in Wounded Heroes. Gier flew to Chicago to interview Dr. Lipov and film the SGB treatment. The segment starts with Dr. Lipov explaining what SGB is, where it originally came from, and how and why it works.

As part of his research for the film, Gier talked to doctors inside and outside of the military that perform SGB on patients and many active duty service members and veterans who have had the procedure. To portray a balanced and accurate understanding of SGB, Gier interviewed Dr. Lipov and Dr. Turabi, an active-duty physician, and asked them on-camera to answer common questions and concerns about SGB for those who are not familiar with the procedure, like questions about its safety and efficacy.

Wounded Heroes was released in March 2021 and has won two film festival awards to date – the "Best Documentary" at the Orlando Film Festival and an Honorable Mention at the New York Movie Awards. For those who want to view the film, it is available on Amazon, iTunes, Google Play, VUDU, Roku, Vimeo, and more.

In 2020, the PenFed Credit Union's Digital Team expressed interest in filming and following three Stella patients who would undergo the SGB procedure. The project was independent of Stella, with all decisions about filming and editing exclusively made by the PenFed Digital Team. Stella's only role was to provide access to three patients.

Two Marine Corps veterans and an ER Nurse who worked in a COVID positive unit during the first surge of the pandemic in New York agreed to participate in the project. Each of them was filmed in Chicago while receiving the SGB treatment, with full access granted to the Operating Room. Following their procedures, their stories were documented over the months to come. At 3 months post-procedure, the film crew did further interviews with each of them, which involved traveling to do in person interviews with both of the Marine Corps veterans. One of these veterans, Sidney Morris, was filmed as he walked the streets of the dangerous neighborhoods in inner city Los Angeles where he had been homeless as a teen. He talked about the dramatic positive healing and his hope for the future as a direct result of the SGB procedure many months prior. The PenFed SGB docu-series received a total of seven Emmy Awards in 2021.<sup>74</sup> Finally, Mission 22 has been producing mini documentaries as part of their larger Network, and they're in the middle of producing stories of two patients who have had SGB prior to entering the Mission 22 "Recovery and Resiliency" Program. Filmmakers interviewed two veterans prior to their SGB procedure, accompanied them into the operating room for live filming of their SGB, and then followed them for several months afterwards to track their recovery journey. While the film is still in production, the filmmakers noted the impacts of SGB on the procedure day. The film will be released in late 2021/early 2022 and will be made available via the Mission 22 Network online.

Stories like these are helping SGB become more visible to those who suffer from trauma symptoms. Filming has been a critical part of de-mystifying the procedure, alleviating common questions and concerns with any new procedure, and helping more people become aware of the relief that SGB may bring.

#### Conclusion

During this time of unprecedented trauma, we must innovate like our lives depend on it -- because they do. Innovation in trauma care is critical, especially right now, when trauma due to the global COVID-19 health crisis is rampant. Those who suffer from trauma deserve the best care we can provide – care that is practical, effective, and informed by modern neuroscience. Stellate Ganglion Block is one of the most promising new treatments for trauma. The combination of SGB with psychological and mindbody wellness practice holds real potential to help many who suffer find lasting relief. To learn more, explore the resources and references that follow.

## Resources

American Psychiatric Association: About Posttraumatic stress disorder (PTSD)

American Psychological Association: PTSD

Department of Veterans Affairs: Use of Benzodiazepines for PTSD

National Institute of Mental Health: About PTSD

National Alliance on Mental Illness: About PTSD

Stella

Erase PTSD Now

The Stellate Institute

WOUNDED HEROES documentary film featuring SGB and other treatments

PEN FED DOCUMENTARY FILM SERIES following SGB patients

## **About Stella**

- The Chief Medical Officer of Stella, Dr. Eugene Lipov, is a world-renowned anesthesiologist and the pioneer of SGB for PTSD who has published multiple articles on SGB. He has treated well over 1,000 patients since 2006 and he leads the training of Stella SGB providers who serve patients within an expanding number of Stella clinics across the nation.
- The Chief Psychologist of Stella, Dr. Shauna Springer, is one the nation's leading psychologists and a trusted advisor to the military and veteran communities. She advances a new model for trauma care that combines SGB and therapy to get optimal outcomes.
- Throughout 2020-2021, Stella has expanded to more than 40 sites across the United States, multiple locations in Australia, and continues to add new sites both in the United States and abroad.

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