The Cost Savings Potential of Pulsed Electromagnetic Field Therapy in the Treatment of Failed Back Surgery Syndrome Pain

EXECUTIVE SUMMARY

Failed back surgery syndrome refers to persistent or recurring back or leg pain following one or more spine surgeries. There are a number of treatment options for failed back surgery syndrome, including conservative and minimally invasive therapies, together forming "usual care", as well as invasive interventions such as implanting spinal cord stimulation devices or performing revision surgeries. However, given the high annual volume of lumbar spine surgeries and an incidence rate as high as 46%, the burden of failed back surgery syndrome on population health and on healthcare system cost is significant.

Although spinal cord stimulation devices and re-operation have not demonstrated superior effectiveness as compared to usual care in the treatment of failed back surgery syndrome, they are associated with significantly higher two-year costs. Specifically, a careful examination of the peer-reviewed literature identified average two-year costs of usual care, spinal cord stimulation, and re-operation procedures as $30,669, $92,618, and $98,248, respectively. Therefore, if a new, non-invasive treatment could allow patients to remain in usual care rather than progressing to surgical alternatives, it could offer both improved patient care as well as cost savings to healthcare payers.

One such treatment alternative is the use of pulsed electromagnetic field therapy (PEMF), a non-invasive therapy using shortwave energy delivery to induce localized analgesic and anti-inflammatory effects. At a cost of up to $7,290 for a 45-day PEMF treatment cycle, we determined that if PEMF could reduce the invasive procedure rate by more than 27.6%, use of PEMF will result in two-year cost savings to the healthcare payer. Results from a single arm, open label, multicenter study of PEMF in failed back surgery syndrome suggest a 72.3% reduction in the invasive procedure rate at 6 months.

Given these findings, it seems likely that use of PEMF in addition to usual care will result in two-year cost savings to the healthcare payer.

REFERENCES

INTRODUCTION

Failed back surgery syndrome (FBSS) refers to persistent or recurring back or leg pain following one or more spine surgeries,\(^1\) including anatomically successful surgeries\(^2\). Etiological factors for FBSS include misdiagnosis, inappropriate patient selection, wrong-level surgery, surgical technical failure, spinal instability, spinal stenosis, epidural fibrosis, recurrent disc herniation, adjacent segment disease, sacroiliac joint pain, and piriformis syndrome.\(^{1,3,5}\) Given the large volume of lumbar spine surgeries performed each year\(^6\) and an FBSS incidence rate between 19% and 46%,\(^1\) the burden of FBSS on population health and on healthcare system cost is significant.

There are a number of treatment options for FBSS, including conservative therapies, minimally invasive treatments, and surgical interventions. Conservative and minimally invasive treatments include pharmacologic management, physical therapy, psychological/educational therapy, epidural steroids, and local anesthetics (e.g., facet medial branch blocks; sacroiliac joint blocks). Taken together, the use of conservative and minimally invasive treatments is what is often termed “usual care” (UC) for FBSS. While UC is preferred over more invasive interventions, the long-term benefit-to-risk profile must be carefully evaluated for any pharmacological interventions.\(^1,7,8,9\)

Surgical options such as implanting spinal cord stimulation (SCS) devices or intrathecal drug delivery pumps and revision surgeries are also utilized to treat FBSS. However, there is a diminishing success rate associated with repeat spinal surgeries\(^1\) and evidence is mixed regarding the effectiveness of SCS for treatment of FBSS.\(^{10,11}\) In fact, a recent study of FBSS patients receiving workers’ compensation reported only 5% of SCS patients and 10% of UC patients met the primary outcome (a composite measure of pain, disability and opioid medication use).\(^{10}\)

Although SCS and re-operation have not demonstrated superior effectiveness as compared to UC in the treatment of FBSS, they are associated with significantly higher two-year costs.\(^{10,12}\) As such, a new, non-invasive treatment that could allow patients to remain in UC rather than progressing to surgical alternatives could offer substantial cost savings to healthcare payers. One such treatment alternative is the use of pulsed electromagnetic field therapy (PEMF), a non-invasive therapy using shortwave energy delivery to induce localized analgesic and anti-inflammatory effects.\(^{13,14}\) While the results of an open-label, single-arm pilot study\(^{15}\) have been reported, the potential of PEMF to reduce payer costs has not been examined.
OBJECTIVE

Estimate the percentage reduction in invasive procedures that PEMF would have to achieve in order to result in cost savings from a payer perspective.

METHODS

To determine a time horizon for our analysis, we performed a preliminary literature search to identify peer-reviewed analyses of the costs and cost-effectiveness of usual care, SCS, and re-operation treatments for FBSS. As most of the analyses identified reported two-year costs and/or cost-effectiveness, we thus chose a two-year payer perspective for our analysis.

Following this preliminary review, we conducted a formal literature search to identify peer-reviewed articles describing costs and/or cost-effectiveness associated with UC, SCS, and re-operation treatments for FBSS. The search was limited to US original studies comparing multiple FBSS treatment options over a two-year period. We thus excluded any studies reporting over a time frame other than two years; any case series reports or other single-arm prospective or retrospective studies; and any studies conducted outside the US.

Utilizing the cost data obtained during this review, we developed conservative assessments of the two-year cost differential between SCS and UC ($CD1$) and the two-year cost differential between re-operation and UC ($CD2$). Given an assumed cost of up to $7,290 ($C = $7,290) for 45 days of PEMF therapy (Provant Therapy System, Regenesis Biomedical, Inc., Scottsdale, AZ, USA), we calculate the estimated maximum percentage reduction necessary to achieve two-year cost parity as $C/[Avg(CD1,CD2) \times \alpha]$, where $\alpha$ is the percentage of FBSS patients who progress from UC to either SCS or re-operation.

RESULTS

The two-year direct medical costs for SCS, re-operation and UC varied by study and are dependent on the medical resource utilization categories included in the study, as well as on the perspective of the study (e.g., Medicare or workers' compensation). Therefore, the results are not collapsed into one summary, but are stratified by intervention (SCS, re-operation, or UC) and then again by study author to facilitate understanding of study-specific differences in cost measurement.
Two-Year Costs of Spinal Cord Stimulation

Hollingworth et al. (2011)\textsuperscript{10}

Hollingworth et al. (2011) conducted a prospective cohort study to evaluate the costs and cost-effectiveness of SCS (as compared to UC and to care provided by a pain clinic) for FBSS in a cohort of workers’ compensation patients over a two-year period. As is standard practice in health economics analyses, all costs were discounted at a rate of 3% after the first year to reflect the positive time preference of individuals (i.e., preferring consumption of resources sooner rather than later). Medical costs were evaluated using actual payments received from third-party payers and thus represent a payer perspective analysis. In this study, 5% of SCS patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use) at two years. Among the 27 patients receiving SCS, five had one or more revision/replacement procedures and five had permanent removal procedures. The mean medical cost per SCS patient ($n = 51$) over two years was $52,091 in 2007 US dollars (as reported) or $66,668 in 2015 US dollars.

Lad et al. (2014)\textsuperscript{12}

Lad et al. (2014) conducted a retrospective analysis of a population-based insurance claims dataset to evaluate the cost of SCS vs. re-operation for the treatment of FBSS. Independent variables utilized in the analysis included sex, insurance, Charlson index, and surgery type. Dependent variables included re-operations; complications; medical resource utilization (inpatient hospitalizations, outpatient services, and prescription medications); and healthcare costs associated with medical resource utilization. At two years post-SCS implantation, the mean two-year costs per SCS patient ($n = 395$) were reported as $80,669 (assumed to be in 2009 US dollars)\textsuperscript{1} or $95,968 in 2015 US dollars.

If we utilize the number of SCS patients in each study to perform a weighted average of the costs identified in Lad et al. (2014) and Hollingworth et al. (2011), we arrive at an average two-year cost associated with SCS of $\textit{92,618}$ (Figure 1).
Two-Year Costs of Re-Operation

Lad et al. (2014)\textsuperscript{12}

Only one study meeting our pre-specified criteria reported costs of re-operation for FBSS. As described above, Lad et al. (2014) describe the findings of a retrospective analysis of an administrative claims dataset comparing SCS vs. re-operation for treatment of FBSS. Two years after the index re-operation procedure, the mean healthcare costs per re-operation patient (n = 395) were $82,586 (assumed to be in 2009 US dollars)\textsuperscript{2} or $98,248 in 2015 US dollars (Figure 1).

Two-Year Costs of Usual Care

Hollingworth et al. (2011)\textsuperscript{10}

As with re-operation, only one study meeting our pre-specified criteria reported costs of UC for FBSS. As described above, Hollingworth et al. (2011) describes a prospective cohort study designed to evaluate the costs and cost-effectiveness of SCS (as compared to UC and to care provided by a pain clinic) for FBSS in a cohort of workers’ compensation patients over a two-year period. In this study, 10\% of UC patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use). Among the 68 patients receiving UC, the mean medical cost per UC patient over two years was $23,964 in 2007 US dollars or $30,669 in 2015 US dollars (Figure 1).

Calculation of Performance Metric to Achieve Cost Savings

We can now calculate the cost differential between SCS and UC as $92,618 - $30,669 = $62,012 (CD1). Similarly, the cost differential between re-operation and UC is $98,248 - $30,669 = $67,579 (CD2). Thus, the average of CD1 and CD2 is approximately $64,796. Given that the cost of PEMF therapy is up to $7,290, it is a straightforward calculation to determine that the estimated maximum percentage reduction necessary to achieve two-year cost parity is: $7,290/($64,796 + α), where α is the percentage of FBSS patients who progress from UC to SCS or to re-operation.

Review of Harper et al. (2014) Study Implications\textsuperscript{15}

Harper et al. (2014) reports the results of an open label, multicenter study of PEMF for treatment of FBSS. The primary objective of this exploratory study was to investigate the analgesic effectiveness of PEMF administered twice daily over a 45-day period in 34 subjects with persistent or recurrent pain following back surgery. A secondary goal of the study was to guide the design of future randomized controlled trials targeting responsive subpopulations.

\textsuperscript{2} Lad et al. (2014) utilized administrative claims data between 2000 and 2009 to arrive at their cost findings. Although it was not indicated, we have assumed that all costs were converted to 2009 US dollars as is standard practice in retrospective administrative claims data analyses.
As a part of the study, subjects were asked prior to receiving PEMF if they had been considering any of the following procedures for treatment of their pain associated with FBSS: re-operation; epidural steroid injections; nerve ablation therapy; SCS implantation; or drug pump implantation. Prior to receiving PEMF, four patients were considering SCS procedures and five patients were considering re-operations. Of these nine patients, only one patient actually proceeded with a re-operation procedure during the 6-month follow-up period. However, two additional patients (i.e., patients not included in the count of nine who were considering invasive procedures at baseline) reported undergoing invasive procedures (one SCS and one re-operation) prior to the 6-month follow-up.

If we were to assume that the nine patients considering invasive procedures would all have received invasive procedures without PEMF treatment and that the two additional PEMF patients receiving invasive procedures would still have received invasive procedures without PEMF treatment, then without PEMF therapy (i.e., utilizing current standard of care (SOC) for FBSS) the rate of invasive procedures in this 27 patient population would have been 11/27 = 40.7%. Knowing that the invasive procedure rate is 40.7%, we determined that the estimated maximum percentage reduction necessary to achieve two-year cost parity was 0.276, or 27.6%, by using the formula derived previously: $7,290/($64,796*0.407). In the PEMF + SOC treatment group, however, only three patients received an invasive treatment in the 6-month follow-up period. The PEMF + SOC treatment group thus had an invasive procedure rate of 3/27 = 11.1% representing a 72.3% reduction in the invasive procedure rate. As a 72.3% reduction in the invasive procedure rate is much higher than our “threshold” reduction of 27.6%, PEMF demonstrates promise in the prevention of costly, invasive procedures for the treatment of FBSS. See Figure 2 for estimated two-year costs associated with SOC and with PEMF + SOC treatment based on the 6-month findings from Harper et al. (2014) as described above.

**DISCUSSION**

Based on the qualitative findings from the prospective case series study described above (Harper et al., 2014), it seems likely that use of PEMF in addition to UC will result in two-year cost savings to the healthcare payer. To provide a definitive answer, a randomized, controlled trial in discectomy patients is underway.

Clearly, there are limitations in our ability to extrapolate the true invasive procedure reduction rate from the follow-up data to the Harper et al. (2014) study. First, and most importantly, the follow-up
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Clearly, there are limitations in our ability to extrapolate the true invasive procedure reduction rate from the follow-up data to the Harper et al. (2014) study. First, and most importantly, the follow-up data is available only through six months and the studies from which the costs of UC, SCS and re-operation were obtained were two-year studies. Given that PEMF patients may experience a return to their baseline pain levels after six months, more patients may proceed to invasive procedures over the ensuing 18 months. However, given the cost differences between UC and invasive treatment alternatives, any delay in the performance of invasive treatments leaves open the opportunity that invasive procedures may not ever be performed. Therefore, avoidance of invasive procedures in the near term may prove to have a lasting cost savings effect. Furthermore, as described above, anything more than a 27.6% reduction in invasive procedures over a two-year period due to a single 45-day treatment program would result in payer cost savings. Therefore, the 72.3% reduction in invasive procedures at 6 months could dwindle over the succeeding 18 months and still result in long-term payer cost reductions. See Figure 3 for the expected per patient two-year cost savings as a function of the percentage reduction in invasive procedures due to a single 45-day treatment program with PEMF.

Finally, rather than utilizing PEMF therapy one time only, another potential strategy to allow patients to remain in UC might be to provide PEMF therapy as frequently as every six months (as needed). It is thus important to understand the conditions under which PEMF therapy would result in payer cost savings even if utilized more frequently by some patients. If we assume a 40.7% invasive procedure rate for patients receiving SOC alone and a 72.3% reduction in invasive procedures due to PEMF therapy, we can use the formula derived previously to calculate the PEMF therapy cost at which cost parity between SOC and SOC + PEMF would be achieved: $0.723 = \frac{C}{(64,796 \times 0.407)}$ or $C = 19,067$. In other words, utilizing our previous assumptions regarding the invasive procedure rate associated with SOC and the reduction in invasive procedures associated with PEMF therapy reported by Harper et al., we find that payer costs for PEMF therapy over two years could average as high as $19,067 per patient (or an average of at least 2.6 six-week courses of PEMF therapy) and still result in a two-year cost savings to the payer. Again, early evidence of PEMF therapy effectiveness suggests this is a very achievable goal.
Figure 1. Two-Year Costs

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Two-Year Cost (2015 US dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-year costs of usual care (UC)</td>
<td>$30,669</td>
</tr>
<tr>
<td>Two-year costs of spinal cord stimulator (SCS)</td>
<td>$92,618</td>
</tr>
<tr>
<td>Two-year costs of re-operation</td>
<td>$98,248</td>
</tr>
</tbody>
</table>

Lad et al. (2014) conducted a retrospective analysis of a population-based insurance claims dataset comparing SCS vs. re-operation for treatment of FBSS. Two years after the index re-operation procedure, the mean healthcare costs per re-operation patient (n = 395) were reported as $80,669 (assumed to be in 2009 US dollars).

As described above, Lad et al. (2014) describe the findings of a retrospective analysis of an administrative claims dataset comparing SCS vs. re-operation for treatment of FBSS. The primary objective of this exploratory study was to investigate the analgesic effectiveness of SCS (as compared to UC and to care provided by a pain clinic) for FBSS in a cohort of workers' compensation patients over a two-year period. In this study, 10% of UC patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use). Among the 68 patients receiving UC, the mean medical cost per UC patient over two years was $23,964 in 2007 US dollars (as reported) or $30,669 in 2015 US dollars.

As with re-operation, only one study meeting our pre-specified criteria reported costs of UC for FBSS. The primary endpoint in this study was an 80% reduction in the percentage of workers’ compensation patients with back pain. Among the 27 patients receiving SCS, five had one or more revision/replacement procedures and five had negative time preference of individuals (i.e., preferring consumption of resources sooner rather than later). Medical costs were evaluated using actual payments received from third-party payers and provided by a pain clinic) for FBSS in a cohort of workers' compensation patients over a two-year period. In this study, 5% of SCS patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use). Among the 68 patients receiving UC, the mean medical cost per UC patient over two years was $23,964 in 2007 US dollars or $30,669 in 2015 US dollars.

Harper et al. (2014) reports the results of an open label, multicenter study of PEMF for treatment of pain following back surgery. A secondary goal of the study was to guide the design of future randomized controlled trials targeting responsive subpopulations. Hollingworth et al. (2011) describes a prospective cohort study designed to evaluate the costs and cost-effectiveness of SCS (as compared to UC and to care provided by a pain clinic) for FBSS in a cohort of workers' compensation patients over a two-year period. In this study, 10% of UC patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use). Among the 68 patients receiving UC, the mean medical cost per UC patient over two years was $23,964 in 2007 US dollars or $30,669 in 2015 US dollars.

We can now calculate the cost differential between SCS and UC as $92,618 - $30,669 = $62,012. Similarly, the cost differential between re-operation and UC is $98,248 - $30,669 = $67,579.

Calculation of Performance Metric to Achieve Cost Savings

If we utilize the number of SCS patients in each study to perform a weighted average of the costs, we find that the percentage reduction necessary to achieve two-year cost parity is: $CD1$ - $CD2$ = $CD3$.

Armed with these findings, we have an intuitive understanding of the efficacy of SCS for FBSS. The percentage of FBSS patients who progress from UC to SCS or to re-operation.
Two-Year Costs of Re-Operation

If we utilize the number of SCS patients in each study to perform a weighted average of the costs identified in Lad et al. (2014) and Hollingworth et al. (2011), we arrive at an average two-year cost associated with SCS of $92,618.

Figure 2. Two-Year Expected Per Patient Costs: Standard of Care vs. PEMF + Standard of Care

$57,159

$45,259

Standard of Care

Standard of Care + PEMF

Assumes 27 patients with FBSS in SOC and PEMF + SOC treatment arms follow treatment trajectories suggested by 6-month PEMF study of Harper et al. (2014). For SOC arm, assumes 5 patients receive SCS, 6 patients have re-operation, and 16 patients remain in UC over 2 years. For PEMF + SOC arm, assumes all 27 patients receive PEMF treatment for 6 weeks, with 2 patients subsequently requiring re-operation, 1 patient subsequently requiring SCS, and the remaining 24 patients remaining in UC over 2 years.
OBJECTIVE
Estimate the percentage reduction in invasive procedures that PEMF would have to achieve in order to result in cost savings from a payer perspective.

METHODS
To determine a time horizon for our analysis, we performed a preliminary literature search to identify peer-reviewed analyses of the costs and cost-effectiveness of usual care, SCS, and re-operation treatments for FBSS. As most of the analyses identified reported two-year costs and/or cost-effectiveness, we thus chose a two-year payer perspective for our analysis.

Following this preliminary review, we conducted a formal literature search to identify peer-reviewed articles describing costs and/or cost-effectiveness associated with UC, SCS, and re-operation treatments for FBSS. The search was limited to US original studies comparing multiple FBSS treatment options over a two-year period. We thus excluded any studies reporting over a time frame other than two years; any case series reports or other single-arm prospective or retrospective studies; and any studies conducted outside the US.

Utilizing the cost data obtained during this review, we developed conservative assessments of the two-year cost differential between SCS and UC ($CD1$) and the two-year cost differential between re-operation and UC ($CD2$). Given an assumed cost of up to $7,290 ($C = $7,290) for 45 days of PEMF therapy (Provant Therapy System, Regenesis Biomedical, Inc., Scottsdale, AZ, USA), we calculate the estimated maximum percentage reduction necessary to achieve two-year cost parity as $C/\text{Avg}(CD1, CD2)\times\alpha$, where $\alpha$ is the percentage of FBSS patients who progress from UC to either SCS or re-operation.

RESULTS
The two-year direct medical costs for SCS, re-operation and UC varied by study and are dependent on the medical resource utilization categories included in the study, as well as on the perspective of the study (e.g., Medicare or workers' compensation). Therefore, the results are not collapsed into one summary, but are stratified by intervention (SCS, re-operation, or UC) and then again by study author to facilitate understanding of study-specific differences in cost measurement.

Figure 3. Two-Year Per Patient Expected Cost Savings with Assumed Percentage Reductions in Invasive Procedures

<table>
<thead>
<tr>
<th>Percent reduction in invasive procedures due to PEMF</th>
<th>Two-year per patient expected cost savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>$0</td>
</tr>
<tr>
<td>20%</td>
<td>$610</td>
</tr>
<tr>
<td>40%</td>
<td>$5,856</td>
</tr>
<tr>
<td>60%</td>
<td>$11,167</td>
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<tr>
<td>80%</td>
<td>$12,000</td>
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Two-Year Costs of Spinal Cord Stimulation
Hollingworth et al. (2011) conducted a prospective cohort study to evaluate the costs and cost-effectiveness of SCS (as compared to UC and to care provided by a pain clinic) for FBSS in a cohort of workers' compensation patients over a two-year period. As is standard practice in health economics analyses, all costs were discounted at a rate of 3% after the first year to reflect the positive time preference of individuals (i.e., preferring consumption of resources sooner rather than later). Medical costs were evaluated using actual payments received from third-party payers and thus represent a payer perspective analysis. In this study, 5% of SCS patients achieved the primary endpoint (a composite measure of pain, disability, and opioid medication use) at two years. Among the 27 patients receiving SCS, five had one or more revision/replacement procedures and five had permanent removal procedures. The mean medical cost per SCS patient (n = 51) over two years was $52,091 in 2007 US dollars (as reported) or $66,668 in 2015 US dollars.

Lad et al. (2014) conducted a retrospective analysis of a population-based insurance claims dataset to evaluate the cost of SCS vs. re-operation for the treatment of FBSS. Independent variables utilized in the analysis included sex, insurance, Charlson index, and surgery type. Dependent variables included re-operations; complications; medical resource utilization (inpatient hospitalizations, outpatient services, and prescription medications); and healthcare costs associated with medical resource utilization. At two years post-SCS implantation, the mean two-year costs per SCS patient (n = 395) were reported as $80,669 (assumed to be in 2009 US dollars) or $95,968 in 2015 US dollars.

If we utilize the number of SCS patients in each study to perform a weighted average of the costs identified in Lad et al. (2014) and Hollingworth et al. (2011), we arrive at an average two-year cost associated with SCS of $92,618 (Figure 1).
Surgical options such as implanting spinal cord stimulation (SCS) devices or intrathecal drug delivery pumps and revision surgeries are also utilized to treat FBSS. However, there is a diminishing success rate associated with repeat spinal surgeries and evidence is mixed regarding the effectiveness of SCS for treatment of FBSS.

Failed back surgery syndrome (FBSS) refers to persistent or recurring back or leg pain following one or more spine surgeries, including anatomically successful surgeries. Etiological factors for FBSS include pharmacologic management, physical therapy, psychological/educational therapy, epidural steroids, and local anesthetics (e.g., facet medial branch blocks; sacroiliac joint blocks). Taken together, the use of conservative and minimally invasive treatments is what is often termed "usual care" and an FBSS incidence rate between 19% and 46%1, the burden of disease, sacroiliac joint pain, and piriformis syndrome. Given the large volume of lumbar spine surgeries performed each year, the economic impact of failed back surgery syndrome (FBSS) has not been examined. Although SCS and re-operation have not demonstrated superior effectiveness as compared to usual care (UC) for FBSS. While UC is preferred over more invasive interventions, the long-term benefit-risk profile must be carefully evaluated for any pharmacological interventions.

One such treatment alternative is the use of pulsed electromagnetic field therapy (PEMF), a non-invasive therapy using shortwave energy delivery to induce localized analgesic and anti-inflammatory effects. PEMF has been shown to be effective in the treatment of chronic pain conditions such as peripheral neuropathy and fibromyalgia. However, the evidence for the effectiveness of PEMF in the treatment of failed back surgery syndrome pain is limited and further research is needed.

A new, non-invasive treatment that could allow patients to remain in UC rather than progressing to surgical alternatives could offer substantial cost savings to healthcare payers. One such treatment includes pharmacologic management, physical therapy, psychological/educational therapy, epidural steroids, and local anesthetics (e.g., facet medial branch blocks; sacroiliac joint blocks). Taken together, the use of conservative and minimally invasive treatments is what is often termed "usual care."
The Cost Savings Potential of Pulsed Electromagnetic Field Therapy in the Treatment of Failed Back Surgery Syndrome Pain

EXECUTIVE SUMMARY

Failed back surgery syndrome refers to persistent or recurring back or leg pain following one or more spine surgeries. There are a number of treatment options for failed back surgery syndrome, including conservative and minimally invasive therapies, together forming "usual care," as well as invasive interventions such as implanting spinal cord stimulation devices or performing revision surgeries. However, given the high annual volume of lumbar spine surgeries and an incidence rate as high as 46%, the burden of failed back surgery syndrome on population health and on healthcare system cost is significant.

Although spinal cord stimulation devices and re-operation have not demonstrated superior effectiveness as compared to usual care in the treatment of failed back surgery syndrome, they are associated with significantly higher two-year costs. Specifically, a careful examination of the peer-reviewed literature identified average two-year costs of usual care, spinal cord stimulation, and re-operation procedures as $30,669, $92,618, and $98,248, respectively. Therefore, if a new, non-invasive treatment could allow patients to remain in usual care rather than progressing to surgical alternatives, it could offer both improved patient care as well as cost savings to healthcare payers.

One such treatment alternative is the use of pulsed electromagnetic field therapy (PEMF), a non-invasive therapy using shortwave energy delivery to induce localized analgesic and anti-inflammatory effects. At a cost of up to $7,290 for a 45-day PEMF treatment cycle, we determined that if PEMF could reduce the invasive procedure rate by more than 27.6%, use of PEMF will result in two-year cost savings to the healthcare payer. Results from a single arm, open label, multicenter study of PEMF in failed back surgery syndrome suggest a 72.3% reduction in the invasive procedure rate at 6 months.

Given these findings, it seems likely that use of PEMF in addition to usual care will result in two-year cost savings to the healthcare payer.

REFERENCES