EXOGEN® Bone Healing System shown to be most cost-effective bone stimulator

Introduction

This study demonstrates that EXOGEN Bone Healing System is the most cost-effective bone stimulator – with an expected cost of $6,610. While unit prices for all stimulators are equal, the higher probability of treatment success with EXOGEN makes follow-up surgery less likely, cutting overall cost. A Monte Carlo Simulation determined that EXOGEN would be the optimal bone treatment system for 85% of patients. Combined, these findings indicate that insurers should consider the cost benefits of expanding coverage for EXOGEN to include concomitant conservative treatment of stable non-union fractures.

Summary of Methods and Findings

Treatment pathways for five different bone stimulators – EXOGEN, Physio-Stim® Lite, OL1000™ Bone Growth Stimulator, OrthoPak®, and EBI Bone Healing System® – were modeled using a decision tree (TreeAge Data v3.0.13). Treatment failures were assumed to require surgery. Probabilities of treatment success came from published literature, manufacturers' data and patient registry data. Cost data came from published literature and Durable Medical Equipment Regional Carriers (DMERCs).

For each stimulator, the expected cost of treating a non-union fracture was calculated. The expected cost of a treatment is the average cost of all possible outcomes from that treatment and is calculated in two steps: First, the cost of each outcome is weighted by the probability that the outcome will occur. Second, the weighted costs are summed to obtain a single cost estimate. For a payor faced with a product reimbursement decision, the expected cost of treatment communicates more about the least costly alternative than the overall cost of treatment.

Products with high probabilities of success have smaller expected costs than products with low probabilities of success, because fewer failures mean fewer surgeries. Fewer surgeries mean lower costs.

EXOGEN had the lowest expected cost ($6,610), followed by Physio-Stim Lite ($8,714). Sensitivity analyses demonstrated expected costs were sensitive to the probability of success: EXOGEN would have the lowest expected cost if its probability of success were at least 0.745, while OL1000 would have the lowest expected cost if its probability of success were at least 0.84. A Monte Carlo simulation showed that EXOGEN was the optimal stimulator for 85% of patients, Physio-Stim Lite for 14%, and EBI Bone Healing System for 1%.

EXOGEN was the least costly bone stimulator for conservatively treated non-union fractures. Public insurers should consider the cost benefits of expanding coverage for EXOGEN to include concomitant conservative treatment of stable non-union fractures.

Bone Stimulator Average Expected Costs for Non-Unions – Figure 1

Greater Success Probability Decreases Surgeries and Lowers Costs

Product	**Unit Cost**	**Surgical Cost** (in case of failure)	**Probability of Success** (range) [source]	**Probability of Failure/ Need for Surgery**	**Expected Cost** (success/failure probability)	**Additional Cost** (in excess of EXOGEN)
EXOGEN®	$2950	$24,892	83% (0.66, 1.0)[5-9]	17%	$6,610	$0
Physio-Stim Lite <3 hrs. day	$2950	$24,892	36% (0.29, 0.43)[1]	64%	$8,714 (usage probabilites combined)	$2,104 (usage probabilites combined)
>3 hrs. day	$2950	$24,892	80% (0.64, 0.96)[1]	20%		
EBI Bone Healing System	$2950	$24,892	64% (0.51, 0.77)[2]	36%	$11,711	$5,101
Orthopak	$2950	$24,892	73% (0.58, 0.88)[3-4]	27%	$9,471	$2,861
OL1000 Bone Growth Stimualtor	$2950	$24,892	75% (0.60, 0.90)[5]	25%	$8,973	$2,363

Assumptions & Features

- The total, per patient cost of surgery to treat delayed union was $24,892 ($20,575 [surgery and recovery] + $4,317 [outpatient costs]).[12] For purposes of this analysis, it was assumed that the same costs would apply to the treatment of non-union fractures. For sensitivity analyses, the cost of surgery was varied by ±50%, which was the range used in an economic analysis of early versus delayed operative treatment in patients with closed tibial shaft fractures.[13] For consistency, the costs of the stimulators were also varied by ±50%.
- Length of follow-up did not affect treatment success.[4]
- Success rates were global, i.e., representative of all fracture sites rather than site-specific.
- No complications from treatment were included in the model.
- The cost of successfully treating a patient with a bone stimulator is the cost of the product ($2,950 for EXOGEN and electrical stimulators).
- The cost of failing to treat a patient with a bone stimulator is the cost of the product plus the cost of surgery.
- Probabilities were selected from sources wherein the specific product could be identified. Probabilities match closely with general review data on bone stimulators.[10,11] Probability ranges were arbitrarily set at ±20% to conduct sensitivity analyses.
- References are for point estimates of probabilities.

Verification Procedures

One-way sensitivity analyses were performed by varying all probabilities by ±0.20 and all costs by ±50%. A Monte Carlo simulation was conducted to determine the optimal bone stimulator for a hypothetical cohort of 10,000 patients. The analysis was undertaken from the perspective of United States Centers for Medicare and Medicaid Services.

Sensitivity Analysis (one-way)

The ranking of products by expected cost generally does not change when the cost of successful treatment or the cost of failed treatment is independently varied by ±50%. The exception is in cases where a bone stimulator other than EXOGEN was used to treat a non-union: if the treatment failed and the cost of providing the failed treatment ranged from $13,821.11 to $18,860.32, then Physio-Stim Lite would have the lowest expected cost.

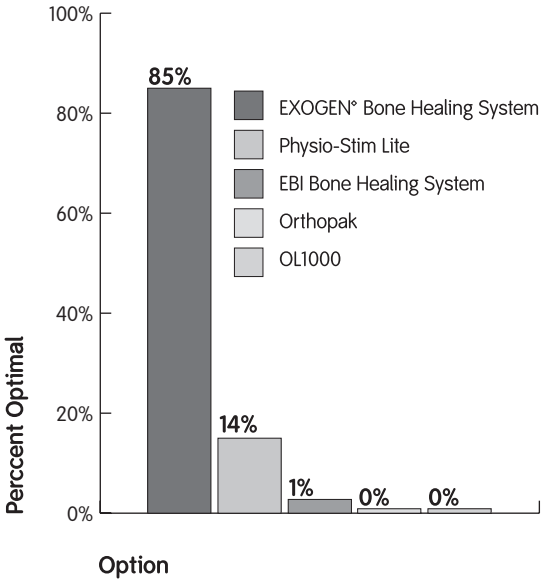
- EXOGEN will have the lowest expected cost as long as its success rate is greater than 76% (assuming the success rates for all other products are held constant).
- Physio-Stim Lite will have the lowest expected cost if its success rate is greater than 89.3% and every patient uses the product for 3+ hours per day (assuming the success rates for all other products are held constant). Physio-StimLite will not have the lowest expected cost if every patient uses the product for <3 hours per day, even if the success rate reaches the upper bound of the range in Table 1 (i.e., 43%). This assumes the success rates for all other products are held constant.
- OL1000 will have the lowest expected cost if its success rate is greater than 84% (assuming the success rates for all other products are held constant).
- OrthoPak will have the lowest expected cost if its success rate is greater than 84.5% (assuming the success rates for all other products are held constant).
- EBI Bone Healing System will not have the lowest expected cost even if its success rate reaches the upper bound of the range in Table 1 (77%). This assumes the success rates for all other products are held constant.

Conclusion

Expected cost is sensitive to changes in product success rates.

Optimal Bone Stimulation Strategy for Hypothetical Subjects – Figure 2

(Orthopak and OL1000 were not optimal for any patients)



Monte Carlo Simulation

A Monte Carlo simulation is an analytical technique in which probability distributions (e.g., normal, log-linear) are assigned to outcomes in a model. The distributions reflect the uncertainty of the outcomes. In Figure 1, the outcomes are average costs based on treatment success and failure probabilities for each bone stimulator. The uncertainty lies in the fact that costs vary from person-to-person. In the Monte Carlo simulation in Figure 2, a hypothetical cohort of subjects was run through the model to estimate treatment costs.

Monte Carlo simulations complement expected cost analyses. An expected cost analysis is used to recommend a certain outcome. A Monte Carlo simulation is used to estimate the percentage of the hypothetical cohort for whom the recommended outcome would be optimal. Hypothetical subjects in the simulation below were 'guided' to optimal outcomes (i.e., least cost outcomes) on the basis of random cost values that were drawn from the probability distributions assigned to each outcome.

Numerical Breakdown of Hypothetical Subjects by Optimal Bone Stimulation Strategy – Figure 3

Product	Successes n (%)	Failures n (%)	Subtotal n (%)	Total
EXOGEN	7,035 83%	1,458 17%	8,493 100%	
Physio-Stim Lite <3 hrs. day	41 34%	78 66%	119 100%	
>3 hrs. day	997 80%	253 20%	1,250 100%	10,000
EBI Bone Healing System	92 69%	46 31%	138 100%	

Assumptions for the bone stimulator simulation

Cost of bone stimulation is normally distributed with a mean of $2,378.56 (EXOGEN) or $2,750.22 (all other stimulators) and a standard deviation of $1,189.28 (EXOGEN) or $1,375.11 (all other stimulators). Cost of surgery is normally distributed with a mean of $24,892 and a standard deviation of $12,446. 10,000 hypothetical subjects were run through the model. The optimal treatment path was re-evaluated for each subject and a predictable random sequence with key value 1,000 was specified to allow the simulation to be replicated in the future.

Results

Based on the criterion of lowest expected cost, EXOGEN would be the recommended stimulator for treating non-union fractures. The Monte Carlo simulation showed that EXOGEN would be the optimal (least costly) treatment for approximately 85% of the 10,000 hypothetical subjects in the cohort. Physio-Stim Lite would be the optimal treatment for 14% of the subjects, and the EBI Bone Healing System would be the optimal treatment for 1% of the subjects. The remaining stimulators (OL1000, OrthoPak) would not be optimal for any subjects.

Schultz M, Oremus M, Whitman CS, Conway JD.
"Cost-effectiveness of Bone Stimulators in the Conservative Treatment of Stable Non-union Fractures."
International Society for Pharmacoeconomics and Outcomes Research, Seventh
Annual European Congress, Hamburg, Germany, October 24-26, 2004.

References

1. Garland DE, Moses B, Salyer W. Long-term follow-up of fracture non-unions treated with PEMFs. Contemp Ortho 1991; 22(3):295-302.

2. EBI LP. EBI Bone Healing System: Summary of EBI PMA P790002. Available at: http://www.ebimedical.com/. Accessed on: Apr. 14, 2004.

3. EBI LP. OrthoPak Bone Growth Stimulator: Indications for Use. Available at: http://www.ebimedical.com/. Accessed on: Apr. 14, 2004.

4. Hinsenkamp M, Ryaby J, Burny F. Treatment of non-union by pulsing electromagnetic field: European multicenter study of 308 cases. Reconstr Surg Traumatol 1985; 19:147-151.

5. Regentek (a division of dj Orthopaedics LLC). OL1000 Bone Growth Stimulator Post-marketing Patient Registry Data. Available at: http://regentek.djortho.com/_docs/RegistryData.pdf. Accessed on: Apr. 14, 2004.

6. Warden SJ, Bennell KL, McMeeken JM, Wark JD. Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (SAFHS): A review. Calcif Tissue In 2000; 66(2):157-163.

7. Frankel VH, Koval KJ, Kummer FJ. Ultrasound treatment of tibial non-unions. American Academy of Orthopaedic Surgeons, 66th Annual Meeting. Anaheim, California, February 4-8, 1999.

8. Heppenstall RB, Frey J, Ryaby J, McCabe J. Noninvasive non-union treatment by pulsed low-intensity ultrasound. 21st Triennial World Congress, Societé Internationale de Chirurgie Orthopédique et de Traumatologie. Sydney, Australia, April 18-23, 1999.

9. Frankel VH. Results of prescription use of pulse ultrasound therapy in fracture management. In: Szabo Z, Lewis JE, Fantini GA, Savalgi RS, editors. Surgical Technology International VII. San Francisco: Universal Medical Press, 1998: 389-393.

10. Gossling HR, Bernstein RA, Abbott J. Treatment of ununited tibial fractures: A comparison of surgery and pulsed electromagnetic fields (PEMF). Orthopedics 1992; 15(6):711-719.

11. Anglen J. The clinical use of bone stimulators. J South Orthop Assoc 2003; 12(2):46-54.

12. Heckman JD, Sarasohn-Kahn J. The economics of treating tibial fractures. The cost of delayed unions. Bull Hosp Joint Dis 1997; 56(1):63-72.

13. Sprague S, Bhandari M. An economic evaluation of early versus delayed operative treatment in patients with closed tibial shaft fractures.

49015017015 71981215 09/05