



Chapter 25

Socioeconomic Impact of Nucleus Arthroplasty™ Procedures

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Key Points

- The role of economics in health care is becoming an increasingly prominent issue and has implications for the development of new technologies.
- Low back pain is a leading cause of health care expenditure in the United States, spurring 10 million physician visits annually.
- Although there has been a remarkable proliferation in the spinal device market over the past 10 years, there remains a significant population of patients with mild to moderate degenerative disc disease who suffer from disabling pain for whom no good treatment options exist.
- By restoring normal spinal biomechanics after discectomy and offering an alternative to fusion in the treatment of discogenic back pain, nucleus arthroplasty technology may offer an improved means of treating back pain with less long-term morbidity, less initial and long-term cost, and quicker return to pre-morbid functional level.

- With accumulating experience, sales of nucleus arthroplasty devices are expected to increase to \$2.25 billion by 2015.
- Economic challenges to be addressed include payer coding mechanisms and adoption and payment by insurance carriers.

INTRODUCTION

Consideration of health economics has now become a prerequisite in the practice of medicine. In our current environment, it is becoming increasingly important for care providers and industry to have an in-depth understanding of the socioeconomic and net health impact of their intended treatment population and available options. This phenomenon is driven by many factors including the growing needs of our aging population and an increased level of scrutiny of the financial information reviewed by insurance carriers.

This chapter will describe trends in patient demographics and historical costs associated with fusion. In addition, it will describe a promising intervention being developed to delay, or avoid, more costly surgical procedures associated with degenerative disc disease.

First and foremost, it is important to note how prevalent lower back pain is within the United States. Although the below statistics do not necessarily address degenerative disc disease only, it is still imperative to understand how many people within the United States actually suffer from back conditions.

- Back pain is a leading cause for health care expenditures in the United States.
- Back pain is the principal reason for doctor visits in the United States, and back pain affects more than 10.0 million people annually.
- Back pain is the principal ailment cited in worker's compensation claims in the United States.
- Back pain is the principal cause of employee absenteeism in the United States.
- More than 220 spinal conditions, indications, and pathologies afflict patients throughout the world.¹

An estimated 30% of people aged 30-50 years old will have some degree of disc space degeneration, although not all will have pain or ever receive a formal diagnosis.² Most of the patients within the above statistics will recover on their own or receive conservative treatment that will alleviate their symptoms. Surgery is utilized only when non-surgical options have failed and when the pain has become uncontrollable and debilitating. It should be noted that

more than one-half of those patients who recover from a back pain experience will have a recurring episode at some point in their life.³ Only 1 to 3% of back pain is related to a herniated disc within the spine, and these may or may not need surgical intervention.⁴ For those where conservative treatment is not effective, and surgical procedures are not yet an option, the patient and treating physicians are left with limited choices. It is these refractory patients that nucleus arthroplasty technology seeks to address.

It is therefore the focus of this chapter to address the limits of current surgical options that were discussed in Chapter 21 and highlight the importance of proper reimbursement for new additions to the degenerative disc disease treatment algorithm.

DEMOGRAPHIC OVERVIEW

Degenerative disc disease (DDD) is defined as an aberrant cell-mediated response to progressive spinal structural failure that is irreversible, always affected by physical and biological mechanisms, and can be associated with mechanical dysfunction and pain. Chapter 21 describes the demographics that pertain to this disease state, amongst which are the progressive aging of the population and early onset of obesity. Both of these conditions contribute to degeneration of the spine. With an 18% increase in the world life expectancy, 7% within more developed countries and 22% in Latin America, the amount of orthopedic procedures is likely to increase.

TREATMENT CONTINUUM

There has been a remarkable proliferation of spinal devices over the past 15 years with a corresponding increase in market size. The spinal market worldwide has grown from \$100 million dollars in 1990 to \$6.5 billion dollars in 2007. This market segment is projected to grow at a rate of 15-20% annually.⁶ A large portion of this growth is attributed to a change in philosophy in the treatment of spinal disorders which has resulted from a greater understanding of spinal biomechanics, mechanisms of spinal degeneration, and the origins of low back pain. An emphasis is now being placed on motion preservation and tissue sparing approaches, two factors which putatively affect short and long-term morbidity in lumbar surgery. Treatment algorithms continue to evolve through the introduction of emerging technologies and procedures. A few examples include: vertebroplasty/kyphoplasty, minimally invasive instrumentation, posterior dynamic stabilization devices, and total disc replacements (TDR).

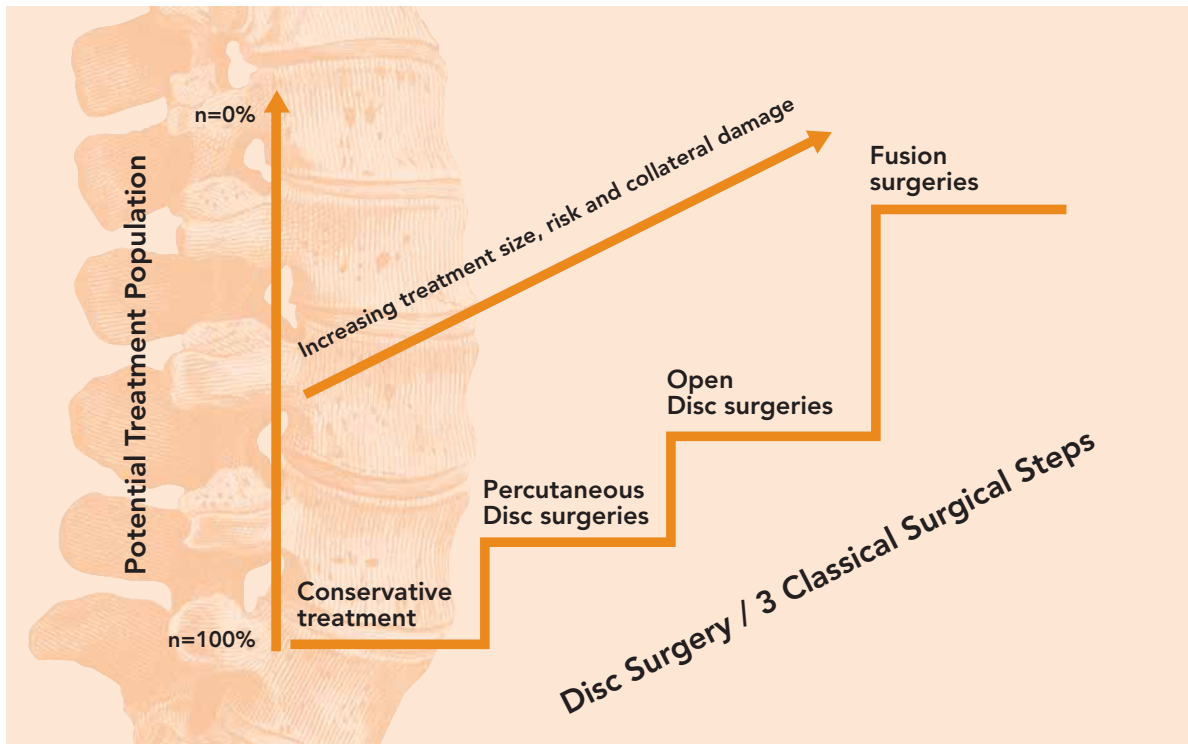


Figure 1
Bertagnoli¹⁰

For those unfortunate enough to experience a spinal injury in the lumbar region, there have historically been few surgical options. Two major gaps in the care continuum become apparent in Figure 1:

1. Gap between conservative care and discectomy.
2. Gap between discectomy and fusion

Consequently, historical treatment options may have resulted in under-treatment when conservative care has been ineffective or over treatment when DDD has not progressed to a level requiring more extensive surgical intervention such as with fusion. Stakeholders (physician, patient, payer, community and others) welcome the innovation of promising technologies designed to address treatment opportunities which better serve the patient, avoid unnecessary services and are proven safe, effective and with a durable response.

Conservative treatment modalities include physical therapy, medication therapy, heat and cold therapy, use of anti-inflammatory and opioid medications. Patients diagnosed with moderate to severe degenerative disc disease may require surgical interventions ranging from total disc arthroplasty to fusion. Discectomies, laminectomies, and fusions have demonstrated

efficacy in the treatment of moderate to severe symptomatic DDD in the absence of improvement after a trial of conservative care. Although these treatments have demonstrated efficacy in selected patients, they are expensive, not right for all patients and do not necessarily correct the underlying problem.

The clinical performance of lumbar fusion for back pain has increased dramatically since the 1980s with the advent of better instrumentation, implants, and bone morphogenic proteins (BMPs). The procedure, although associated with significant short-term costs, may be economically beneficial as surgical patients have been shown to return to work in greater proportion than those managed conservatively.^{7,8} Patients undergoing fusion procedures, however, may be at a higher long-term risk for developing adjacent-level degeneration which may cause future disability, necessitate further surgical intervention and contribute to greater overall cost.

Total disc replacement devices are now available which promise to restore motion and regional biomechanics. Although often thought of as an expensive option, costs to payers and hospitals may be significantly less overall when compared with common fusion constructs.⁹ Longer-term health economic and utilization outcome study is required to evaluate long-term durability and net health impact upon patient care, quality of life, functional improvement, and cumulative cost.

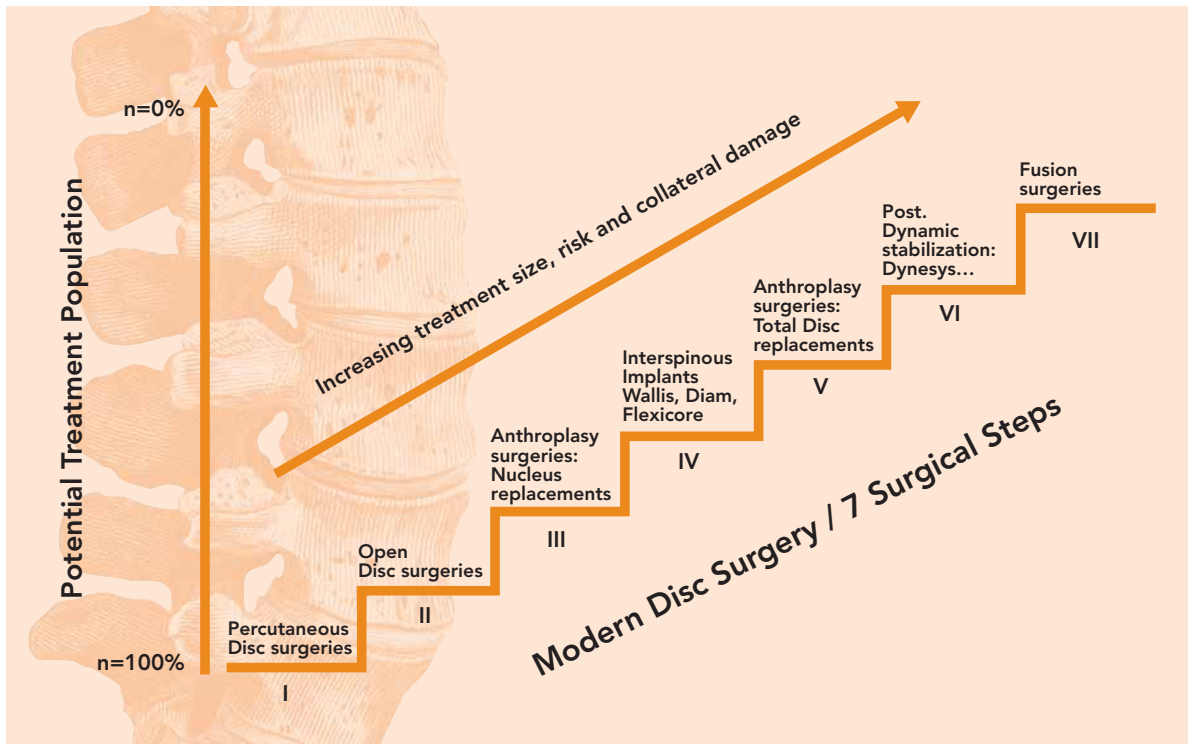


Figure 2
Bertagnoli¹⁰

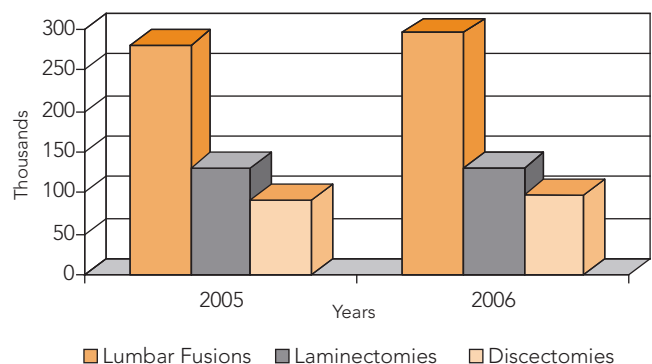
Despite these advances, current surgical options are not universally beneficial and there remains a large group of patients who are poorly served. This group includes patients with mild to moderate DDD who fail conservative management but whose pathology does not warrant total disc replacement or fusion (Figure 2).

Nucleus arthroplasty technologies were developed to provide a minimally or less-invasive surgical option to treat low back pain associated with mild-moderate DDD, while preserving natural motion and anatomic structures (i.e. annulus, endplate). Although no nucleus arthroplasty technology is on the U.S. market yet, the first is expected to receive FDA approval by 2011. Nucleus arthroplasty procedures may also be used prophylactically after discectomy to restore normal segmental biomechanics and prevent or forestall the development of degenerative changes at the same or adjacent levels. In this manner, nucleus arthroplasty may prove to be an extremely valuable tool in the reduction of direct and indirect costs associated with back pain. As with other interventions, it will be prudent to measure the long-term durability of nucleus arthroplasty procedures, evaluating the impact upon total cost of care and the ability to delay (or avoid) the need for more invasive and complex procedures associated with this patient segment diagnosed with DDD.

COMMON SPINE PROCEDURES

In 2005, there were approximately 278,000 thoracolumbar fusions performed in the United States. Additionally, 129,000 independently performed laminectomies and 92,000 discectomies were performed this same year. Increases in procedure rates are expected as the overall population continues to age. Using major data resources, *Orthopedic Network News* estimates that by 2006, these procedures will increase by 5.8%, 1.9%, and 5.3%, respectively (Figure 3). In the aggregate, these numbers will increase by 4.6%.

US In-patient Spinal Procedures 2005-2006



Orthopedic Network News, Volume 17, Number 4, October 2006

Figure 3

Key Diagnoses Relating To In-patient Spinal Repair Procedures - 2001

<u>ICD Procedure</u>	<u>ICD</u>	<u>Diagnosis</u>	<u>Occurrence</u>	<u>Percent</u>
3.02 Reopen laminectomy site	722.10	Lumbar disc displacement	331	40%
	724.02	Spinal stenosis, lumbar	314	38%
	722.83	Post-laminectomy syndrome, lumbar	79	10%
	721.30	Lumbosacral spondylosis	52	6%
	729.20	Neuralgia/neuritis, nos	42	5%
	Total		818	100%
3.09 Spinal canal exploration, nec	724.02	Spinal stenosis, lumbar	50,656	70%
	721.30	Lumbosacral spondylosis	7,436	10%
	722.10	Lumbar disc displacement	6,173	9%
	723.00	Spinal stenosis, cervical	4,297	6%
	721.10	Cervical spondylosis w/myelopathy	3,534	5%
	Total		72,096	100%
80.51 Intervertebral disc excision	722.10	Lumbar disc displacement	141,853	83%
	722.00	Cervical disc displacement	14,397	8%
	724.02	Spinal stenosis, lumbar	7,092	4%
	722.73	Lumbar disc disease w/myelopathy	4,086	2%
	722.52	Lumbar/lumbosacral disc degeneration	2,870	2%
	Total		170,298	100%
81.06 Lumbar fusion 81.08	722.10	Lumbar disc displacement	22,362	27%
	722.52	Lumbar/lumbosacral disc degeneration	20,132	24%
	724.02	Spinal stenosis, lumbar	16,228	20%
	738.40	Acquired spondylolisthesis	14,553	18%
	721.30	Lumbosacral spondylosis	8,973	11%
	Total		82,248	100%

Source: Knowledge Enterprise, Inc. 2002

Figure 4

MedPAR national in-patient hospital data for the year 2005 reveals \$3.7 billion in charges for thoracolumbar fusion. Remaining fusion procedures totaled over \$1.7 billion. Other spine-related procedures totaled \$3.4 billion.¹¹

On average, reimbursement for a single level fusion procedure is approximately \$13,558, an increase from an average reimbursement rate of \$5,688 six years ago.⁺ While data continues to be compiled, projected fusion procedure costs within the United States in 2006 are estimated to be \$732,900,000.¹² Variability in this estimate is predicated upon the complexity of each case and implants used during each procedure.¹³

Although the elderly population in the world is increasing and orthopedic healthcare costs will certainly rise, it is imperative to note that those over 65 years of age are not the ones who are getting most of the procedures. According to *Orthopedic Network News*, only 29% of all laminectomies and excisions were performed on patients over age 65, while 23% of all fusion cases were performed on patients in this same population. Younger patients therefore present the greater burden of illness and will require costly care over a longer period of time.

Given that the onset of DDD generally occurs when a person is between 30 and 50 years of age, it is quite important to commence treatment early so that the pain does not recur or become more problematic. While most patients will not need surgical treatment, those who do warrant surgical intervention may not necessarily need a fusion, as discectomies and laminectomies may not correct the problem. Nucleus arthroplasty technology will then act as an earlier stage treatment for those who require surgical intervention.

As can be seen from the chart above, 70% of all laminectomies had spinal stenosis associated with the procedure, and 83% of all discectomies had lumbar disc displacement as the top diagnosis. This chart demonstrates which diagnoses are most commonly associated with various spinal procedures. This will be important to monitor as more surgical technologies and procedures come on the market. A question remaining to be answered is: Will the advent of nucleus arthroplasty technologies increase or decrease the use of laminectomies or discectomies? (Figure 4)

*DRG codes used in this analysis are: DRG 9, DRG 497, DRG 498, DRG 499, DRG 500, DRG 519, DRG 520, DRG 531, and DRG 532

+Fusion implants include metals, bone graft, autograft, interbody fusion devices and BMP

Key Procedures Relating To In-patient Back Problems - 2001


ICD Diagnosis	ICD	Procedure	Occurrence	Percent
722.10 Lumbar disc displacement	80.51	Intervertebral disc excision	141,853	82%
	81.08	Posterior lumbar fusion	16,167	9%
	3.09	Spinal canal exploration, nec	6,173	4%
	3.92	Injection into spinal canal, nec	5,868	3%
	81.06	Anterior lumbar fusion	3,597	2%
	Total		173,658	100%
722.52 Lumbar/lumbosacral disc degeneration	81.08	Posterior lumbar fusion	13,088	49%
	81.06	Anterior lumbar fusion	5,463	21%
	3.09	Spinal canal exploration, nec	3,202	12%
	80.51	Intervertebral disc excision	2,870	11%
	3.92	Injection into spinal canal, nec	1,883	7%
Total		26,506	100%	
722.73 Lumbar disc disorder with myelopathy	80.51	Intervertebral disc excision	4,086	70%
	81.08	Posterior lumbar fusion	814	14%
	3.09	Spinal canal exploration, nec	483	8%
	3.92	Injection into spinal canal, nec	257	4%
	81.07	Lateral transverse lumbar fusion	172	3%
Total		5,812	100%	
722.83 Post-laminectomy syndrome, lumbar	81.08	Posterior lumbar fusion	1,338	36%
	3.90	Insertion, catheter, spinal canal	863	23%
	3.93	Insertion, spinal neurostimulator	583	16%
	86.06	Insertion, infusion pump	485	13%
	3.09	Spinal canal exploration, nec	404	11%
Total		3,673	100%	
724.00- Spinal stenosis 724.09	3.09	Spinal canal exploration, nec	50,656	67%
	81.08	Posterior lumbar fusion	12,797	17%
	80.51	Intervertebral disc excision	7,092	9%
	81.07	Lateral transverse lumbar fusion	2,773	4%
	3.92	Injection into spinal canal, nec	2,426	3%
Total		75,744	100%	

Source: Knowledge Enterprise, Inc. 2002

Figure 5

Another important aspect to the above chart is that lumbar fusion is most commonly associated with disc displacement, disc degeneration, and spinal stenosis. This implies that other surgical procedures and technologies are currently being evaluated within the worldwide spinal community that may tend to lower the frequency in which fusion is utilized for degenerative disc disease. Although such technologies are currently not approved in the United States, should they be successful in Europe and Asia, the number of fusion procedures will likely decrease. The anticipated decrease in the use of fusion creates a win-win situation for both patient and surgeon. In addition, it will ultimately lower the cost borne by the public sector as these new technologies are expected to carry a lower price tag.

The chart above compares the diagnosis to the procedure that is most commonly associated with it. As can be seen, to treat lumbar disc displacement, i.e., herniation, discectomy is used 82% of the time. To treat disc degeneration, fusion is used 70%. For these diagnoses, over 50% of the patients are between 40 and 64 years of age. Given the problems associated with fusion procedures, for young patients, it should not be the first resource for a surgical treatment. It can be extrapolated that perhaps if surgeons had a different and validated surgical procedure—something outside of fusion—they would choose it over such invasive surgeries (Figure 5).



NUCLEUS ARTHROPLASTY TECHNOLOGY IS A PROMISING TECHNOLOGY WHICH, WHEN PROVEN SAFE AND EFFECTIVE, MAY ADDRESS A TREATMENT VOID FOR PATIENTS WITH MILD TO MODERATE DDD.

Another interesting point on this graph is that to treat post-laminectomy syndrome, surgeons choose fusion 36% of the time. Although the following point may not be confirmed until we monitor surgeon behavior, surgeons might tend to lean to a less invasive procedure, such as nucleus arthroplasty, or another form of treatment that is not yet on the U.S. market.

LESS INVASIVE PROCEDURES: NUCLEUS ARTHROPLASTY

Refinement of current treatment algorithms for DDD will require continuing revision as development of new technologies are proven to be safe and effective. For example, inclusion of less invasive interventions such as nucleus arthroplasty will eventually require consideration. Avoiding unnecessary fusions, while providing medically necessary interventions for patients with mild to moderate stenosis, will address the current void in treatment algorithms. Given the nature of the implant and use in patients who are refractory to conservative care, nucleus arthroplasty will likely result in lower overall costs due to avoidance or deferral of more invasive procedures. Unlike fusion procedures described above, an average nucleus arthroplasty procedure is expected to cost in the range of \$5,000 to \$6,000.¹⁴

International sales of nucleus arthroplasty devices are expected to increase over the next five to seven years with industry revenues expected to be approximately \$2.25 billion by 2015.¹⁵ While there are currently no United States FDA-approved nucleus arthroplasty devices, several have been approved for implantation under an IDE clinical trial. Payer coding mechanisms must be established, as well as education, adoption (coverage), and payment by insurance carriers which support access to nucleus arthroplasty devices for appropriate patient populations.

CONCLUSION

Nucleus arthroplasty technology is a promising technology which, when proven safe and effective, may address a treatment void for patients with mild to moderate DDD. Longer-term clinical and economic outcomes studies, comparative effectiveness trials and refinement of surgical technique, surgical training, and appropriate patient selection will be required. Throughout this process, stakeholder engagement, including major payers, health care providers, employer coalitions, and the manufacturing industry must work in concert to ensure patient access to emerging technologies, while addressing community need for quality, cost-effective care.

REFERENCES

1. Dynawell Back Pain Statistics. http://www.dynawell.biz/clin_spin_back.asp.
2. <http://www.spine-health.com/topics/cd/overview/lumbar/young/degen01.html>.
3. <http://www.neurology.health-cares.net/lower-back-pain.php>.
4. <http://www.spineuniverse.com/displayarticle.php/article1932.html>.
5. UN World Population Prospects.
6. Viscogliosi Brothers, LLC company estimates.
7. Moller H, Hedlund R. Surgery versus conservative management in adult isthmic spondylolisthesis—a prospective randomized study: part 1. *Spine*, 2000. 25(13): p. 1711-5.
8. Fritzell P, et al. 2001 Volvo Award Winner in Clinical Studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: a multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine*, 2001. 26(23): p. 2521-32; discussion 2532-4.
9. Guyer, RD, Tromanhauser, SG, Regan, JJ. An economic model of one-level lumbar arthroplasty versus fusion. *Spine J*, 2006.
10. Orthopedic Network News, Volume 17, Number 4, October 2006.
11. Center for Medicare and Medicaid Services. MEDPAR Data 2005.
12. Ibid.
13. Ibid.
14. Viscogliosi Brothers, LLC company estimates.
15. Viscogliosi Brothers, LLC company estimates.