Cleveland Radiology
ASSOCIATES

AUG 17 2007

Dear sirs:

I am writing you in regards to Medicare's proposed payment for FDG PET procedures under the Hospital Outpatient Prospective Payment System for Calendar Year 2008.

I appreciate the hard work and careful consideration CMS put into developing the proposed rule and am aware of the rate and payment method for PET services that CMS has set forth in the Federal Register. In response to the agency's request for public comments on this issue, I would like to urge CMS to retain current Medicare payment for these critical services as a separate payment for the radiopharmaceutical and for the technical component. The proposed payment reductions for PET radiopharmaceuticals will have limiting effects on beneficiary access to PET services.

Proposed bundling of RP into the technical payment would drastically reduce the reimbursement rate for PET scans for patients with cancer and these reductions would significantly diminish access to PET for Medicare patients. We are very concerned that many PET programs simply cannot sustain such a substantial reduction in Medicare payment again in a single year and still continue to provide high quality services. The potential result would be a significant reduction in access to PET for Medicare beneficiaries.

PET's unique ability to provide physicians with information about the body's chemistry, cell function, and location of disease can eliminate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to physicians the most effective mode of treatment. PET can evaluate tissue metabolism to determine the presence or absence of malignancy whereas anatomic imaging depends on size and location of lesions to determine likelihood of malignancy.

The clinical benefits of this technology are enormous, as are the costs of continuing to offer this service. They include the initial expenditure for the medical equipment, renovations to the facility, and the cost to employ highly trained dedicated staff that are increasingly difficult to recruit. The radiopharmaceutical FDG has a very short half-life and facilities need to purchase sufficient quantities to administer to patients. The proposed bundling of RP into the technical component would represent a significant decrease in total reimbursement for FDG PET.

I believe that the Cost to Charge Ratio has only this year possibly begun to be utilized appropriately to accurately reflect the cost of supplying PET radiopharmaceuticals.

I appreciate the opportunity to submit and discuss these comments with you.

Sincerely yours,

H. Lebron Lackey, Jr. MD

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Cleveland, TN 37320

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"OPPS: Packaged Services "

The topic of payment bundling is discussed in this document that has been presented for comments for the upcoming year.

1) CY2008 Packaging Proposal on Payment of CPT Codes 93325, 93350, 93017, dealing with Echocardiology has taken the payment of $98.18 on a Doppler color flow, add on dependent service to zero payment for 2008.

   Naturally, color Doppler is required as part of an examination to identify particular vessel flows. The question in this area is: Will there be any additional increases to the other two HCPCS charges? It is necessary in every echo procedure to use the Doppler colorflow to identify the nature of the vessel origins and such. The wage adjustment APC payment is $98.12 for our facility.

2) The opportunity to charge for IV Contrast is also in question, which is absolutely needed in some of the examination done within the Imaging Department. Without the contrast certain anatomically structure could not be identified. The cost of the contrast is quite high and I believe it would be a potential large sum of money to the organization without the ability to have some type of a *pass-on* charge. Will there be any change in reimbursement for the w/contrast exams?

3) In Nuclear Medicine, radioactive isotope is utilized for every examination. Once again, we have a significant dollar amount attached to the radioactive isotope throughout the annual period. I would ask the same question as to what the opportunities for increases in payment are going to be in light of the bundling of the radioactive isotopes.

4) The modality guidance required for biopsy is the other topic included in the proposed changes. The modality guidance in the past has been somewhat formulated along the lines of the modalities. For instance, ultrasound guided biopsy of the liver had a significantly lower payment than a CT guided biopsy. This is all related to the appropriateness of the machinery and the dollar amounts that that machinery may cost the institution. Example, the CT Scanner runs approximately $1,200,000 vs. a fluoroscopy room at $450,000 or an ultrasound unit at $180,000 and should be reimbursed at different levels due to the choice of modality for that biopsy. This may bring you from the top end of CT Scan through to what is the least expensive of the ultrasound units.

   The decision for biopsy is typically made by the physician, depending on the potential site, the nature of the tumor, and best visualization by modality. Over the years, certain modalities have been identified as being more suitable for imagery in specific areas of the anatomy. For instance, you may be able to find a lesion on the CT Scanner that you may not find on an ultrasound unit. I believe this is strongly taken into consideration when making decisions for biopsy within the institution. Once again, I would ask what is the opportunity for new HCPCS codes and their reimbursements. In the past, codes have been broken down by anatomical structures or regions. August 2, 2007August 2, 2007

The first read and review of the new document is leading me to believe that the codes we are currently using for CT, ultrasound or fluoroscopy guided studies will be eliminated and potentially not replaced with any particular code that would match the biopsy itself.

These HCPCS codes are built in a manner of identifying the modality which the biopsy or aspiration would be done, as well as the anatomical location, as mentioned above. If that code is not going to be used, there is nothing else in the HCPCS description that would allow us to continue to charge for a biopsy or aspiration procedure. In all three instances, I do feel this contributes to a negative bottom line for the hospital and in some ways I am at a disadvantage by not having the availability to be able to see what the newly proposed code structure may look like.

I would appreciate it if you could answer this question in general or possibly lead me to a website where it may be already described. My email is JHreha@MTH.org. I await any help you can give me on this topic.

John Hreha, RT
Director/Imaging Services
08/01/07

3

"OPPS: Packaged Services "

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John Hreha, RT
Director/Imaging Services
08/01/07

Cleveland Radiology ASSOCIATES

Drugs

(4)

AUG 17 2007

Dear sirs:

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UNIVERSITY *of* CALIFORNIA, SAN DIEGO
MEDICAL CENTER

5

William G. Bradley Jr., MD, PhD, FACR
Professor and Chairman
wgbradley@ucsd.edu

August 21, 2007

Leslie V. Norwalk, Esq.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Administrator Norwalk:

Our hospital has reviewed the CMS proposed rule (CMS-1392-P) for Hospital Outpatient Prospective Payment System payment rates for calendar year 2008. Our facility currently owns the equipment to offer the Magnetic Resonance guided Focused Ultrasound (MRgFUS) procedure to patient with uterine fibroids. We submit these comments in response to the proposed CMS rule for 2007 in reference to the MRgFUS procedure.

CMS has proposed to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43. It is our opinion the payment rate for this procedure has, and continues to be, far below the cost incurred by our hospital to provide this service. Average hospital charges for the MRgFUS procedure performed by our hospital range from **$18,000 to $25,000.** The costs of this procedure tend to range from **$8,200 to $9,000**.

Uterine fibroids (leiomyomas) are non-cancerous tumors of the uterus that may cause heavy bleeding, pelvic discomfort and pain and create pressure on other organs. In the United States, 30% of all women between the ages of 25 and 50 are diagnosed with symptomatic uterine fibroids. 400,000 women annually undergo a surgical procedure to relieve the symptoms of uterine fibroids.

Hysterectomy is currently the primary treatment option for uterine fibroids. Hysterectomy is an invasive surgical procedure and is a very expensive procedure for the hospital as well as the health care system. While the clinical results are highly efficacious, there are several drawbacks that cannot be overlooked. Invasive surgery carries with it the risks associated with anesthesia, a high degree of pain post-surgery; and a recovery period of

DEPARTMENT OF RADIOLOGY
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six to eight weeks, during which patients are unable to complete normal activities. It is also an expensive procedure that incurs many direct and indirect costs.

The MRgFUS procedure (HCPCS 0071T and 0072T) offers patients a non-surgical treatment option that allows them to return to normal activities the following day. Patients who undergo the MRgFUS procedure have fewer disability days (decreased days of missed work or days in bed) and lower use of medical resources.

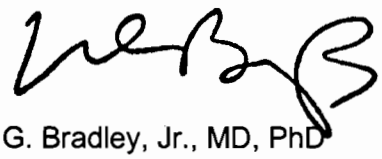
The hospital reimbursement does not always pay for services provided at 100% of actual cost, however, APC classifications should appropriately group services that are similar both clinically and in terms of the resources they require. The proposed APC 0067 does not appropriately reflect the cost of the MRgFUS treatment planning and delivery required to treat patients. When performing Stereotactic Radiosurgery procedures that have been mapped to the same APC, our hospital is permitted to report separate treatment planning procedure codes for plans performed on a date of service prior to treatment delivery. MRgFUS treatment planning is performed immediately prior to treatment delivery and does not separate treatment planning coding available. We cannot perform the MRgFUS procedure without the development of a comprehensive treatment plan. The cost of treatment planning must be captured as part of the APC assignment.

It has been recommended that the most appropriate APC assignment for MRgFUS based upon clinical and resource homogeneity is APC 0127. Reclassification of 0071T and 0072T to APC 0127 would permit our hospital to continue to offer this treatment to our patients.

We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 for calendar year 2008 which more accurately reflects our hospital charges and costs.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,
University of California, San Diego
UCSD Medical Center



William G. Bradley, Jr., MD, PhD
Professor and Chairman

6-0
(189)

P. O. Box 99 • Opelousas, LA 70571-0099 • Phone 337-948-5100 • Fax 337-948-5171

August 24, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

Opelousas General Health System, The Wound Treatment Center, LLC appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Opelousas General Health System, The Wound Treatment Center, LLC is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

The WOUND TREATMENT CENTER
"Entropy Stops Here"

P. O. Box 99 • Opelousas, LA 70571-0099 • Phone 337-948-5100 • Fax 337-948-5171

We believe the discrepancy between proposed payment and resource use has occurred because of a coding change implemented by the AMA in 2006. In January 2006, the AMA created new CPT codes 15340 and 15341 for the application of Apligraf. These two codes replaced three prior codes (15342, 15343, and 15000) used to describe work associated with application of Apligraf. There has been substantial confusion on proper allocation of costs and adjustment of charges to these new CPT codes.

Due to this confusion, the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Marcus S. Speyrer, RN, CWS at (337)948-5100.

Sincerely,

Marcus S. Speyrer, RN, CWS

CALYPSO MEDICAL

www.calypsomedical.com

August 15, 2007

Carol Bazell, M.D.
Director, Division of Outpatient Care
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **OPPS: Packaged Services**

Calypso Medical appreciates the opportunity to comment on the Hospital Outpatient Prospective Payment System Proposed Rule (the Proposed Rule) for Calendar Year 2008. We currently market the Calypso® 4D Localization System (the Calypso System), a system that allows radiation oncologists to minimize the likelihood of unnecessary radiation damage to healthy tissue by providing accurate, objective, and continuous target localization throughout the delivery of radiation. This comment letter addresses CMS's proposal to package payment for guidance services. Calypso Medical is concerned that the Proposed Rule will hinder patient access to critical new technology for patients undergoing radiation therapy, including the Calypso System.

Background on Calypso 4D Localization System

The Calypso System provides continuous, real-time alignment and monitoring of tumor position through the use of small devices (Beacon® Electromagnetic Transponders) implanted in or adjacent to the tumor receiving radiation, in conjunction with a proprietary electronic system that generates and records continuous electromagnetic signals from the transponders. As a result, the technology ensures sub-millimeter level accuracy and precise tumor position information with respect to the linear accelerator radiation beam. By allowing physicians to more confidently deliver radiation to the tumor, this product can provide increased clinical benefits to patients in terms of improved treatment of

the tumor and less radiation to healthy tissue, resulting in an expected reduction in co-morbidities. The Calypso System was approved by the FDA in 2006 for initial use in patients undergoing radiation treatment for prostate cancer. It is presently in use at 15 radiation therapy centers in the United States including MD Anderson Cancer Center Orlando, University of Michigan, University of Pennsylvania, and University of Nebraska, and will expand to approximately 35 leading radiation therapy centers by the end of 2007.

The Calypso 4D Localization System represents a significant clinical improvement over conventional methods for patient positioning and is the only method to monitor organ motion during actual treatment delivery. The key health benefits for Medicare beneficiaries undergoing external beam radiation therapy for prostate cancer include:

- the elimination of unnecessary, non-therapeutic, ionizing radiation from x-ray and CT based patient positioning systems;
- the potential for the reduction of radiation-induced complications to nearby organs such as acute and chronic urinary and rectal incontinence, rectal bleeding, and impotence often associated with radiation treatment for prostate cancer; and
- the potential for improved tumor control by ensuring that the tumor target always receives the full dose and course of radiation.

Recently published clinical studies demonstrate the clinical benefits of the Calypso 4D Localization System compared to existing methods for treatment setup. Existing guidance methods only provide a subjective snap-shot perspective of the position of the tumor prior to the delivery of radiation. Therefore, with existing technology, the clinician is unable to objectively determine the position of the tumor at the start of treatment and cannot monitor target tissue motion during treatment, thereby raising the likelihood of irradiating healthy tissue adjacent to the tumor. Furthermore with existing x-ray based patient positioning systems, the patient is exposed to daily doses of unnecessary, non-therapeutic, ionizing radiation when the clinician x-rays the patient before treatment sessions to locate the tumor.

New Technology APC Application

In August 2006, Calypso Medical submitted:

- an application for a New Technology APC for the daily treatment setup and monitoring necessary for the Calypso 4D Localization System, and

- an application for a Transitional Pass-Through Payment for the permanently implanted Beacon® electromagnetic transponders.

Both applications were submitted with extensive supporting clinical and economic data.

In the Proposed Rule, CMS notes that these two special payment programs are designed "to provide appropriate and consistent payment for designated new procedures that are not yet reflected in [CMS] claims data." Calypso Medical appreciates the availability of these programs, which provide critical incentives for the adoption of new technology that offers the possibility of better clinical experiences and the potential to reduce the total cost of care for Medicare beneficiaries.

Calypso Medical, along with outside clinical experts from the University of Nebraska and Swedish Cancer Institute, met with CMS in May 2007 to review the recent clinical data and answer any additional questions that CMS had regarding the applications and associated information.

To date, CMS has not ruled on these two applications. We respectfully request that CMS grant the New Tech APC and Pass-Through applications and assign temporary HCPCS codes and payment rates for these services.

Packaging for Guidance Services

In the Proposed Rule, CMS proposes to package payment for HCPCS codes for supportive guidance services, such as ultrasonic, fluoroscopic, and stereotactic navigation services, into the payment for the associated primary diagnostic or therapeutic modalities in which they are used. Specifically, CMS proposes packaging the guidance codes because it believes that these services "are typically ancillary and supportive" to the associated modality, and, "in those cases, are an integral part of the primary service they support."

Accordingly, most of these HCPCS codes would be identified as "always integral to the performance of the primary modality" and the associated costs would be packaged into the costs of the separately paid primary services with which they

are billed. While integral to radiation treatment, the patient characteristics that require guidance are different. For example, patients receiving high doses of targeted radiation but there is increased risk of damaging adjacent organs (as is the case with prostate cancer). Such highly conformal treatments require precise patient setup and cotninuous monitoring throughout treatment to minimize complications. The guidance services for highlight conformal treatments are more costly compared to treatments that deliver a broader field. Under this proposal, hospitals may no longer receive a separate payment for guidance procedures for radiation treatment for disease states such as prostate cancer, and reimbursement would be packaged in the payment rate for the radiation treatment procedure codes.

Packaging of Guidance Technology Will Discourage Use of Novel and Clinically Effective Technology

Under the proposal, hospitals would receive the same payment for radiation treatment regardless of the type of guidance technology used to align the radiation beam. Calypso Medical is concerned that the proposed packaging creates a disincentive for hospitals to adopt important novel technologies with clinical advantages if they may be more costly than existing and less effective guidance alternatives such as the use of skin tattoos as treatment localization markers. In the Proposed Rule, CMS acknowledges that hospitals have several options regarding the performance and types of guidance services they use, and stated that it does not want to create payment incentives for hospitals to prefer one form of guidance instead of another, yet this is precisely what the packaging approach will do. According to the proposed rule, packaging will encourage hospitals "to utilize the most cost effective and clinically advantageous method of guidance that is appropriate in each system." However, the proposed packaging does not provide an incentive for hospitals to use clinically superior devices, particularly when less effective devices represent sunk costs and lower expenses.

Existing payment levels for guidance devices such as cone-beam CT, stereoscopic kV x-ray, or ultrasound do not adequately represent the costs and resource use of beacon transponders and daily electromagnetic localization and monitoring

If hospitals are discouraged from using new technology due to insufficient reimbursement levels, the cost and charge data will be slow to reflect the appropriate level of adoption of clinically effective new technology. This

reinforcing cycle will present a barrier to beneficiary access for even longer than the typical two to three years that New Tech APC and Pass-Through payments are designed to be available.

Electromagnetic localization and tracking is a rapidly emerging technology and should not be included in any packaged payments.

Conclusion

To ensure patients receive the most effective medical care for prostate cancer, Calypso Medical respectfully requests that in the Final Rule the agency delay packaging guidance services and continues to set separate payment for individual guidance technologies.

Calypso Medical respectfully requests that CMS provide separate payment for the Calypso 4D Localization System and its associated Beacon transponders for guidance services through a New Tech APC assignment and Pass-Through Device Category. Without separate reimbursement, hospitals will delay using new technologies, forcing providers to rely on less clinically effective methods of tumor positioning and localization, thereby resulting in less cost-effective solutions.

Respectfully,

Eric R. Meier
CEO, President
Calypso Medical Technologies, Inc.

(8)

Valley Baptist

August 22, 2007

Valley Baptist Health System
P.O. Drawer 2588
Harlingen, TX 78551

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

Re: OPPS: Drug Administration, page 470---Comments on reimbursement issues concerning medication administration:

A. The complex drug administration CPT codes place an unfair burden on the provider. Examples:

1. The first intravenous push is coded as CPT 90774. Each additional intravenous push is coded as 90775. Exception: if there is an infusion charge, then 90774 is not used, 90775 is used instead.
2. CPT 90760 is reported for intravenous infusion, hydration; initial, up to one hour. CPT 90761 intravenous infusion, hydration; each additional hour is used for each additional hour unless there is a different initial service (90765, 90774, 96409, or 96413). Then 90760 is not used, 90761 is used instead.
3. Reimbursement rules (from CPT coding) state that each substance/drug should be charged not each injection. So if morphine is given by intravenous injection five times, it is only charged and reimbursed once. Please consider the problem of counting each drug on each record (but ignoring the actual number of injections when charging) and the related problem of automating the charge process.

B. National Correct Coding Initiative edits bundle the administration of medication with the procedure as in the case of cardiopulmonary resuscitation. Separate charges for the administration of the drugs given during the procedure are prohibited. To accurately capture this exception requires a manual process.

C. Infusion time can be prolonged to increase reimbursement. Example: Two hours of infusion pay more than one hour of infusion. Many times this makes no difference to clinical outcome or resources used, yet the payment is increased. If reimbursement must be time based, the time should be calculated using the physician's order and/or pharmacy specified administration time.

Accurate medication administration coding and charge capture are hindered by complex requirements. It is incumbent upon CMS to provide a structure that does not place an unreasonable burden on the provider. The complex rules of CPT coding linked to reimbursement for infusions and injections thwart the development of automated processes, encourage abuse, and impede reimbursement for the service provided.

Sincerely,

Catherine Mezmar

Catherine Mezmar, R.N., M.S.N.,CMAS, CCS
APC Coordinator

(9)

DIXON HUGHES PLLC
Certified Public Accountants and Advisors

August 27, 2007

Centers of Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P (NECESSARY PROVIDER CAHs)
P.O. Box 8011
Baltimore, MD 21244-1850

RE: NECESSARY PROVIDER CAHs

To Whom It May Concern:

This letter contains the comments of Dixon Hughes PLLC related to the notice of proposed rulemaking for Hospital Outpatient Prospective Payment System (OPPS) that includes proposals specific to Critical Access Hospitals (CAH). This proposed rulemaking was published in the Federal Register on August 2, 2007 and will be effective January 1, 2008 if implemented.

Dixon Hughes PLLC (DH) is a Certified Public Accounting and Consulting firm. DH is among the top 20 CPA firms in the country. DH has a significant healthcare practice rendering a wide range of accounting and consulting services to clients throughout the country. DH is associated with over 100 Critical Access Hospitals (CAH) in over 20 states. Consequently, we have significant experience in the financial and operational affairs of CAHs.

We are very concerned about the provisions in the proposed rule which will eliminate the potential of a necessary provider, or any CAH, to establish a provider-based location including a department, a remote (off campus) location or an off campus distinct part psychiatric or rehabilitation unit on or after January 1, 2008 that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for establishing such a unit can be the loss of CAH certification. CMS proposes "...any off campus locations must satisfy the current statutory CAH distance requirements, without exception and regardless of whether the main provider CAH is a necessary provider CAH." This proposal has significant potential to create a negative situation for many CAHs and will consequently negatively impact access to care for Medicare beneficiaries in many rural communities.

We believe that potential access will be diminished in many rural communities because those areas are experiencing an increasing inability to recruit or retain physicians in private practice, non-provider-based practices. This is the result of many factors such as:

- the aging physician workforce,
- inadequate numbers of medical graduates targeted to rural areas because most graduate medical education programs are targeted to urban training,
- insufficient Medicare and Medicaid payments for free-standing physicians on the fee schedule,
- inadequate Medicare and Medicaid payments to free-standing Rural Health Clinics (RHC),

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- increasing amounts of uncompensated care being provided in economically depressed rural communities, and
- other localized factors throughout the country.

In an effort to overcome these recruitment and retention challenges, many rural hospitals (including CAHs) are developing programs that will envelop the rural primary care practices within the hospital's organizational, financial and operational structure (i.e. provider-based scenario). In these cases hospitals are employing physicians or otherwise guaranteeing their income and benefits through contractual arrangements in order to attract and/or retain them in the community. In some cases, the practice locations are being expanded to provide therapy, laboratory, radiology and other diagnostic services in order to maximize access and minimize travel problems for the rural poor and elderly. Other situations develop because there is inadequate space on the CAH campus for expanded services. Therefore the CAH is required to go "off-campus" to provide much needed services. In many cases, these "off-campus" community-based sites will be within 35 miles of another hospital in the case of a necessary provider CAH.

Because Medicare cost reports require hospital overhead be allocated to the operations of the hospital-owned practices, fee-based payments are insufficient to cover both the direct cost of operations and the allocated overhead. Therefore, the cost-based reimbursement of provider-based status is necessary for the financial sustainability of both the practice and the CAH.

We have also experienced clients that are part of a controlled group or network that act with an intentional spirit of collaboration in which they seek to provide the best services and access in the most efficient and cost effective way. These enterprises have created "off campus" facilities in rural communities, within 35 miles of another CAH or hospital with the full collaboration of the neighboring entity. Under the proposed regulations, this type collaborative effort that is a goal of the Flex Program will be stymied. The result will be a continuation of inefficient, duplicative points of access to care or in worse case scenarios beneficiary access will be inhibited.

We recognize CMS has a duty and interest to protect the public from unwarranted "gaming" of the cost-based Medicare (and Medicaid in some states) payment system. However, we believe the proposed regulations are too restrictive. In an effort to create a more reasonable criterion, we believe there should be a test similar to that contained in the existing provider-based regulations that demonstrates a "high level of integration" with the main provider (i.e. the CAH or necessary provider CAH). The test contained in §413.65(e)(3)(iii) – (iv) otherwise known as the 75/75 test, is intended to demonstrate that the proposed facility or organization has or will have a high level of integration with the main provider.

We also believe that the current provider-based attestation standards contained in §413.65 should be used by the CAH to gain approval by the Intermediary of the proposed facility or organization. We believe the attestation may be filed in advance of the creation or acquisition of the off campus facility or organization if the CAH wishes to be held harmless for any subsequent adverse finding. We believe the CAH could also determine that it meets the provider-based regulations, including the high level of integration criteria, and establish the off campus facility or

organization and file the attestation after the initiation of services at the off campus site. In this case, a future adverse determination by the Intermediary would subject the CAH to the refund of the difference in Medicare, and Medicaid if applicable, reimbursement between the cost-based CAH and the applicable fee schedule.

Because we have had experiences of what we believe have been unreasonably lengthy periods of time for the Intermediary response to attestation requests, we believe that Intermediary determination of provider-based status based on submitted attestation requests should be required within a reasonable period of time (such as 60 days from the date of submission). In the event that the Intermediary fails to respond within the specified time, the approval of provider-based status should be deemed to be granted.

We also believe that moving the location of off campus physical facilities, within a reasonable proximity of an existing off campus facility that is a provider-based facility or organization, should be excluded from any future test of distance or "high integration".

We believe that "on campus" patient service functions owned and controlled by the CAH or necessary provider CAH should clearly be exempted from the tests of distance from other hospitals or high level of integration tests.

Thank you for your consideration of these matters. If you have questions concerning these comments, please contact me at 336-714-8100 or tbarnhart@dixon-hughes.com.

Sincerely,

Tommy L. Barnhart, CPA
Member

UNIVERSITY of VIRGINIA HEALTH SYSTEM

DEPARTMENT of NEUROLOGICAL SURGERY

(10)

August 23, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As Professor of Neurosurgery of the Department of Neurosurgery at the University of Virginia Health System I am pleased that CMS offers the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians promoting this technology to patients. We believe that this technology has tremendous potential to improve health outcomes, and the uterine fibroid application is only the first of many to come.

I welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment
5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

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However the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized by the hospitals.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

N. F. Kassell, M.D.

(11)

Bristol-Myers Squibb Medical Imaging 331 Treble Cove Road North Billerica MA 01862 Tel 800.362.2668 www.bmsmi.com

29 August 2007

Mr. Herbert B. Kuhn
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1392-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

RE: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates
CMS-1392-P
Comment on: Packaged Services and OPPS: Packaging Drugs and Biologicals

Dear Mr. Kuhn:

Bristol-Myers Squibb Medical Imaging (BMSMI) appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the above-captioned Proposed Rule updating the Medicare Hospital Outpatient Prospective Payment System ("HOPPS").[1] A subsidiary of Bristol-Myers Squibb Company (BMS)—the global pharmaceutical and related health care products company—BMSMI is one of the leading manufacturers of radiopharmaceuticals and other medical imaging drugs, including DEFINITY® (Vial for [Perflutren Lipid Microsphere] Injectable Suspension), a medical imaging drug used to enhance and delineate cardiac structures during echocardiography procedures.[2]

In these comments, BMSMI raises serious concerns with CMS's proposal to package ("bundle") the Medicare payment for contrast agents, like DEFINITY®*, into the payment for the corresponding echocardiography procedure. This proposed policy is unreasonable for the following reasons:

1. It ignores the fact that the echocardiography procedure codes do not describe the use of contrast imaging drugs—unlike codes for other imaging procedures with contrast enhancement. There is no 1:1 relationship between echocardiography contrast agents and echocardiography procedures as there is with other contrast agents and their associated imaging procedures.

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* Please note that a separate comment letter is being submitted to CMS by BMSMI with respect to the 2008 proposed Medicare HOPPS payment for radiopharmaceuticals.

[1] 72 Fed Reg. 42,628 (Aug. 2, 2007).

[2] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

2. The cost of contrast imaging drugs and contrast administration is substantial relative to the cost of unenhanced echocardiography procedures. Packaging the cost of the contrast agent into the cost of the echocardiography procedure means hospitals will have to bear the cost of (1) the echocardiography procedure, (2) the contrast agent, and (3) the intravenous administration of contrast—all under a payment amount that reflects the costs of the echocardiography procedure alone and none of the costs of the other two components. This will create a significant financial disincentive against use of echocardiography contrast imaging drugs.

3. Echocardiography contrast imaging drugs are used to enhance images when unenhanced images are suboptimal, which occurs in up to 20-percent of rest echocardiograms[3] and up to 30-percent of stress echocardiograms[4]. Use of echocardiography contrast agents may avoid the need for additional diagnostic testing by converting uninterpretable images into interpretable examinations. Without separate payment for contrast imaging drugs, Medicare patient access to contrast-enhanced echocardiography may be jeopardized, and there may be fewer *diagnostic* echocardiograms. This may result in delays in diagnosis and may require Medicare patients to undergo more invasive procedures to obtain a diagnosis.

4. Current Correct Coding Initiative (CCI) policy, which inappropriately bundles/packages the payment for contrast administration into the payment for the echocardiography procedure, has already contributed to substantially lower utilization of contrast agents than is considered appropriate by expert consensus guidelines. Market research data indicate that contrast is used in less than 4-percent of echocardiography procedures in Medicare hospital outpatients despite published guidelines indicating that up to 20-30% of echocardiograms are suboptimal and, therefore, potentially appropriate for contrast use. Packaging the contrast agent into the payment for the echocardiography procedure is likely to result in even lower utilization of contrast agents and may make it not economically feasible for hospitals to continue to use these agents at all.

5. Packaging the payment for contrast agents into the payment for the echocardiography procedure may actually increase Medicare program costs by increasing the likelihood that additional testing will be required when unenhanced images are suboptimal. This would defeat CMS's objective in proposing expanded packaging under HOPPS—it would increase utilization of services under HOPPS rather than helping to control utilization.

6. CMS is required to pay for echocardiography contrast agents, which are separately covered outpatient drugs ("SCODs"), at amounts sufficient to cover hospital acquisition costs. Packaging entire classes of SCODs is not consistent with the congressional mandate under the Medicare Modernization Act to ensure that SCODs are paid at appropriate amounts under HOPPS.

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[3]Waggoner AD, Ehler D, Adams D, *et al.* Guidelines for the cardiac sonographer in the performance of contrast echocardiography: Recommendations of the American Society of Echocardiography Council on cardiac sonography. *J Am Soc Echocardiogr.* 2001;14:417-20.

[4] American Society of Echocardiography Task Force on Standards and Guidelines for the Use of Ultrasonic Contrast in Echocardiography. Contrast echocardiography: current and future applications. *J Am Soc Echocardiogr* 2000;13:331-342.

We request, therefore, that CMS (1) withdraw its proposal to package payment for echocardiography contrast agents and (2) retain current policy of paying separately for these agents. If CMS proceeds with packaging of echocardiography contrast agents, it should create separate contrast-enhanced echocardiography procedure codes for use in the hospital outpatient setting to assure that payments for these contrast enhanced procedures accurately reflect the substantial differences in costs from unenhanced echocardiography procedures.[5]

We also support comments made by the Biotechnology Industry Organization[6] and others that all separately coded drugs, radiopharmaceuticals and biologicals—including contrast agents— should be paid separately under HOPPS. This would avoid the disincentive to perform procedures in the hospital outpatient setting created through different payment policies for injectable drugs, radiopharmaceuticals and biologicals between physician office and hospital outpatient settings.

I. Background on Echocardiography Contrast Agents and their Coding and Payment

Echocardiography procedures are used to evaluate patients with various cardiac disorders. In most cases, echocardiographic images can be interpreted by physicians, and the information can be used in patient management. In 20- to 30-percent of cases, however, echocardiographic images are suboptimal and repeat studies or additional testing may be required. Echocardiographic imaging contrast drugs are FDA-approved intravenously-administered drugs that can enhance images in patients with suboptimal echocardiographic images.[7] Clinical studies have shown that echocardiographic contrast agents can salvage up to 58-91-percent of unevaluable images.[8] Published papers have estimated that substantial cost savings can be obtained from use of echocardiography contrast in cases with suboptimal unenhanced echocardiograms.[9]

Despite the 20 to 30-percent prevalence of suboptimal echocardiograms where contrast enhancement would be indicated as medically appropriate, utilization surveys indicate that less than 4-percent of echocardiography procedures performed in hospital patient settings in patients above the age of 65 involve use of contrast agents.[10] Although the reasons for the substantial underutilization of contrast agents are not certain, one important factor is the current bundling of the intravenous administration procedure into the payment for the echocardiography procedure under the CCI edits. As we have indicated in comments to CMS in the past, this CCI policy, which was implemented in January 2006, imposes a significant financial burden on hospitals offering contrast-enhanced echocardiography and creates a substantial disincentive to use of contrast agents.

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[5] This appears to be required under Soc. Sec. Act. § 1833(t)(2)(G): "[T]he Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not." (42 U.S.C. § 1395l(t)(2)(G)).

[6] Testimony submitted to the Advisory Panel on Ambulatory Payment Classification Groups September 2007.

[7] Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

[8] Package insert for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension (September 2004).

[9] Shaw LJ, Gillam L, Feinstein S, *et al.* Use of an intravenous contrast agent (Optison™) to enhance echocardiography: efficacy and cost implications. *Am J Man Care.* 1998;4: SP169-SP176.

[10] The Echocardiography Market Guide: 2006 United States Editions, Arlington Medical Resources, Inc., Malvern, PA

No echocardiography procedure codes describe the use of contrast. This is unlike the situation with other contrast-enhanced procedures where the codes clearly comprehend the use of contrast. The table below compares the rest echocardiography procedure code (93307) and codes for contrast-enhanced magnetic resonance imaging of the chest and contrast-enhanced computed tomographic imaging of the chest:

Code	Descriptor
93307	Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete
71270	Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections
71552	Magnetic resonance (e.g., proton) imaging, chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s), followed by contrast material(s) and further sequences

(Underlining added in the descriptors above)

Whereas contrast agents are used 100-percent of the time when codes 71270 and 71552 are reported, contrast agents are used less than 4-percent of the time when code 93307 is reported.

II. Echocardiography Contrast Agents Do Not Meet CMS's Criteria for Packaging

In the Proposed Rule, CMS explains its rationale for proposing to package all contrast agents as follows: (1) "[C]ontrast agents are particularly well suited for packaging because they are always provided in support of an independent diagnostic or therapeutic procedure that involves imaging;"[11] (2) "[T]he vast majority of contrast agents billed would already be packaged under the HOPPS in CY 2008, [therefore] we believe it would be desirable to package payment for the remaining contrast agents as it promotes efficiency and results in a consistent payment policy across products that may be used in many of the same independent procedures;"[12]. (3) "[T]he significant costs associated with [the] 15 contrast agents [that otherwise would be packaged under the proposed $60 threshold] would already be reflected in the proposed median costs for those independent procedures and, if we were to pay for the 5 remaining agents separately, we would be treating [the] 5 agents [that would not be packaged under the proposed $60 threshold] differently than the others. If the 5 agents remained separately payable, there would effectively be two payments for contrast agents when these 5 agents were billed—a separate payment and a payment for packaged contrast agents that was part of the procedure payment."[13] This rationale fails when applied to echocardiography contrast agents, like DEFINITY®.

As explained above, other contrast imaging agents—e.g., low osmolar or high osmolar contrast agents used in computed tomography procedures, gadolinium agents used in magnetic resonance imaging—are used 100-percent of the time with the corresponding imaging procedure codes because these codes

[11] 72 Fed Reg. at 42,672.

[12] Id.

[13] Id.

specify use of contrast. This is not the case with echocardiography contrast agents—no echocardiography procedure code describes the use of contrast, and contrast is used in a very small percentage of echocardiography procedures. Therefore, there is no 1:1 relationship between the imaging agent and the procedure with echocardiography procedures.

Unlike most other contrast agents, the echocardiography contrast agents would not be packaged under the proposed $60 packaging threshold for CY2008. There are 3 echocardiography contrast agents listed in the Proposed Rule: (1) Q9955 "Injection, perflexane lipid microspheres, per ml," (2) Q9956 "Injection, octafluoropropane microspheres, per ml," (3) Q9957 "Injection, perflutren lipid microspheres, per ml" (DEFINITY®). The Proposed Rule indicates that code Q9955 would be packaged under the $60 threshold, but codes Q9956 and Q9957 would not be packaged under that threshold. However, perflexane lipid microspheres (Imagent) is no longer commercially available in the U.S. so there is no echocardiography contrast agent that would be packaged under the $60 threshold. Therefore, maintaining separate payment for echocardiography contrast agents will provide consistent payment across this class of contrast agents—both Q9956 and Q9957 would be paid separately. It should be emphasized that echocardiography contrast agents are not interchangeable with the kinds of contrast agents used in radiographic, magnetic resonance or nuclear medicine procedures. Therefore, maintaining separate payment for echocardiography contrast agents would not result in inconsistent payment policies among contrast agents used in any particular imaging procedure.

Market research data indicate that there have been essentially no echocardiography procedures performed with perflexane lipid microspheres since 2005. CMS's own claims data indicate that utilization of perflexane represented less than 1.5-percent of echocardiography contrast utilization in the 2006 outpatient claims database. Therefore, almost none of the costs of the commercially available agents would be reflected in the median costs for echocardiography procedures under the proposed $60 threshold. There would be no "double payments" for echocardiography contrast agents if CMS removes echocardiography contrast agents from the packaging decision for 2008. If the agents are packaged, there will be zero payment. Only by maintaining separate payment will the agents be paid appropriately (once).

We also note that any disparity among products due to their falling above or below the $60 threshold for separate payment is simply a result of the CMS policy to impose such a threshold for separate payment of separately coded drugs, radiopharmaceuticals and biologicals. We support comments made by BIO and others that all separately coded drugs, radiopharmaceuticals and biologicals—including contrast imaging drugs—should be paid separately under HOPPS. This would avoid the potential disparity among like situated drugs furnished in hospital outpatient settings under HOPPS and avoid disparity in payment between the physician office and hospital outpatient settings for injectable drugs, radiopharmaceuticals and biologicals.

III. Packaging Echocardiography Contrast Agents into the Payment for Echocardiography Procedures Will Put a Significant Cost Burden on Hospitals that Use Contrast, when Medically Necessary to Salvage Uninterpretable Examinations.

One of the bases for packaging under HOPPS is where the cost of an item or service is relatively small compared with the cost of the primary service to which the ancillary item or service will be packaged. In

the case of echocardiography contrast agents, the cost of the imaging agent is not insubstantial. The table below shows the median costs for the echocardiography procedure and the contrast agent from the cost files posted by CMS to support the 2008 Proposed Rule[14]:

Component	Code/Descriptor	Median Cost
Echo procedure	93307 "Echo exam of heart"	$414.44
Contrast Agent	Q9957 "Inj perflutren lip micros,ml" (x2mL)	$119.82
	Total	**$534.26**

These data indicate that the contrast agent comprises nearly one-quarter of the total cost of the echocardiography procedure plus the contrast agent. The proposed payment rate of $419.79 is consistent with the claims-based estimated median cost of the procedure, but does not provide any meaningful contribution to cover the cost of the contrast agent notwithstanding the ~$120 incremental cost for the contrast agent. This is not surprising because contrast is used in less than 4-percent of cases and would not be expected to have any impact on the median cost or the payment rate for the procedure.

The 2007 HOPPS payment amount already includes a financial disincentive to use of contrast through the CCI edit bundling the costs for the intravenous administration of contrast into the payment for the echocardiography procedure. As we have indicated in previous comments to CMS, the cost for intravenous administration is not insubstantial: a nurse is required to place an intravenous line and inject contrast (unlike radiographers, sonographers are generally not qualified to start intravenous lines or to administer contrast), and intravenous set up supplies are required. We have maintained that these costs are not captured in the cost of the echocardiography procedure because intravenous access is not required to perform echocardiography, and use of contrast occurs in only a small percentage of procedures. The bundling of the contrast administration has already contributed to the low utilization of contrast—i.e., contrast is used in less than 4% of echocardiography studies, as compared to the up to 20-30% of studies with suboptimal images, in which the use of a contrast agent could be considered appropriate.

If CMS packages the contrast agent as well, hospitals who use contrast agents will have to fund the incremental cost of the contrast agent as well as the incremental cost of contrast agent administration under a payment amount that does not reflect either of these components. Utilization of contrast is likely to fall even lower than current levels, which would mean fewer suboptimal examinations will be salvaged through use of contrast. The net result is likely to be reduced patient access to contrast-enhanced procedures, delays in diagnosis and greater utilization of diagnostic tests overall as patients with suboptimal examinations undergo additional testing because a definitive diagnosis or plan could not be made from the suboptimal examination. Therefore, the packaging of the contrast may have an impact opposite that intended by CMS—increase in overall utilization of diagnostic studies.

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[14] CMS1392P_median_file_by_HCPCS[1].zip and CMS1392P_Drug_Median_File[1].zip. http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1201238&intNumPerPage=10 (accessed August 3, 2007).

IV. Under the Medicare Modernization Act, Congress Mandated that Specified Covered Outpatient Drugs (SCODs) be Paid at Average Hospital Acquisition Cost. Congress Did not Intend for CMS to Package Whole Classes of SCODs without Regard for the Cost

In the Medicare Modernization Act (P.L. 108-173), Congress set down specific requirements for payment under HOPPS of drugs and biologicals. Beginning with 2006, drugs and biologicals that were paid separately as of December 31, 2002 are to be paid at "average acquisition cost" or "if hospital acquisition cost data are not available, the average price for the drug in the year established [for payment in the physician office]."[15] Drugs eligible for payment under this provision are "separately covered outpatient drugs" or SCODs, which are defined to include:

"[A] covered outpatient drug (as defined in section 1927(k)(2)) for which a separate ambulatory payment classification group (APC) has been established and that is -- . . . a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002."

Echocardiography contrast agents, like DEFINITY®, meet the criteria for payment as a SCOD.

- DEFINITY® is a "covered outpatient drug" as defined under Soc. Sec. Act. §1927(k)(2), which includes "[A] drug which may be dispensed only upon prescription . . ., and -- which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Acts." DEFINITY® is a prescription drug and was approved as a new drug under section 505 of the Federal Food, Drug and Cosmetic Act.

- A separate ambulatory payment classification group has been established for DEFINITY®—APC 9112 "Inj perflutren lip micros,ml."

- Pass-through payments were made for DEFINITY® under code C9112 beginning April 1, 2002.

Therefore, DEFINITY® should be eligible for separate payment at hospital acquisition cost (or at the rate paid in the physician office setting) like all other SCODs.

CMS observes correctly in the Proposed Rule[16] that Congress mandated a reduction in the threshold for separate payment under HOPPS to $50-per administration for 2005 and 2006 leaving CMS free to set its own cost threshold for separate payment thereafter.[17] However, it is unreasonable to infer that Congress intended to authorize CMS to package entire classes of SCODs. In the MMA, Congress was mandating a reduction in the cost threshold from $150 to $50 for 2005 and 2006. The clear intent is to allow CMS to set a distinct cost threshold for 2007 and beyond—but not to nullify the SCOD payment provision by packaging entire classes of SCODs.

The proposal to package all contrast agents—including the commercially available echocardiography contrast agents which exceed the cost threshold set for 2007—is unreasonable and inconsistent with the framework for payment of SCODs carefully set out by Congress in the MMA.

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[15] Soc. Sec. Act § 1833(t)(14)(A)(iii) (42 U.S.C. § 1395l(t)(14)(A)(iii)).

.[16] 72 Fed Reg at 42,737

[17] Soc. Sec. Act § 1833(t)(16)(B) (42 U.S.C. § 1395l(t)(16)(B)).

V. Summary and Recommendations.

As explained above, echocardiography contrast agents meet the criteria for separate payment as SCODs under HOPPS. Unlike other contrast agents, echocardiography contrast agents are not associated 1:1 with the corresponding imaging procedures. The costs related to echocardiography contrast agents are not reflected in the median costs for echocardiography procedures; therefore, packaging the payment for echocardiography contrast agents into the payment for the echocardiography procedures would mean that hospitals would incur substantial incremental costs for contrast and contrast administration without any incremental payment. It is unacceptable to point to the low utilization of contrast to argue that hospitals will not be losing much money if echocardiography contrast agents are not paid separately. Utilization of these agents is substantially less than the 20-30% echocardiography studies with suboptimal images for which contrast agents may be appropriate, due in part, to bundling of the payment for the intravenous administration of these drugs under the CCI edits adopted in 2006. If CMS proceeds with its proposal to package the payment for the contrast agent as well, it is likely that utilization will drop lower—some hospitals may discontinue use of contrast agents in echocardiography altogether. Medicare patient access to contrast-enhanced echocardiography may be jeopardized by this proposal, there may be in delays in diagnosis, and patients may be required to undergo more invasive procedures to obtain a diagnosis. This would have an impact on the Medicare program opposite to that intended by CMS with its proposed expansion in packaging—utilization of diagnostic services would be expected to increase as physicians order additional testing when unenhanced echocardiograms are suboptimal. CMS policies should be encouraging appropriate use of echocardiography—not create financial disincentives that penalize those hospitals that use the agents appropriately.

Therefore, we strongly urge CMS to maintain separate payment for echocardiography contrast agents under HOPPS consistent with separate payment for other SCODs. However, if CMS would proceed with its proposal to package echocardiography contrast agents, we would recommend that CMS adopt discrete codes to report contrast enhanced echocardiography procedures to assure that payment accurately reflects the incremental costs for contrast and contrast administration. We also support separate payment for all separately coded drugs, radiopharmaceuticals and biologicals—including all contrast imaging drugs—under HOPPS.

* * * *

BMSMI appreciates the opportunity to comment on the HOPPS Proposed Rule for CY 2008. If you have any questions about these comments, please contact Jack Slosky, Ph.D., M.B.A., at 978-671-8191 or by electronic mail at jack.slosky@bms.com. Thank you.

Sincerely yours,

T Ravenscroft Jr

Timothy Ravenscroft
President,
Bristol-Meyers Squibb Medical Imaging

Cc: American College of Cardiology
American Society of Echocardiography

THE UNIVERSITY of TEXAS
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August 27, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Ms. Norwalk:

I am a practicing Cardiologist and Medical Director of the Division of Cardiology at Memorial Hermann Hospital's Heart and Vascular Institute-Texas Medical Center, Houston Texas.

I previously was responsible for the echocardiography laboratory at Northwestern Memorial Hospital/Northwestern University for 18 years prior to coming to the University of Texas Health Science Center at Houston and Memorial Hermann Hospital.

Echocardiographic contrast agents are critical components for many echo exams. These agents provide optimal imaging in a small but significant number of patients who have poor echo windows. This prevents the need for more expensive nuclear or cath based imaging procedures.

The difficulty with this CMS proposal is that if separate payment for echo contrast agents is eliminated for hospital outpatients; I and many others believe that this will reduce patient access to echo contrast agents. This will ultimately mean that further expensive and unnecessary imaging tests, (nuclear studies, cardiac CT studies, angiograms) will increase as a result of this. This will be a big cost drain to the Medicare System. Therefore I request that the payment not be bundled and continue as a separate payment for echo contrast agents.

Yours truly,

David McPherson, M.D.

David D. McPherson, M.D.

CTMC
CENTRAL TEXAS
MEDICAL CENTER

A Member of Adventist Health System

(13)

August 14, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P. O. Box 8011
Baltimore, TX 21244-1850

Dear Sirs:

CMS published notice recently on the proposed 2008 rates for hospitals. In reviewing the proposal, we noticed with concern the significantly reduced APS rates for outpatient psychiatric services, including the rates for Partial Hospitalization (APC 0033) and Group Psychotherapy (APC 0325).

Central Texas Medical Center offers structured outpatient psychiatric services through the services of our hospital department and its multi-disciplinary team. Guided by the Local Coverage Determination of our Intermediary, we have designed services to provide a flexible continuum of care which offers vital services to the community and hospital. This program treats patients who have disorders which have not responded to office-based care from primary care physicians or from mental health providers in the community. Without the availability of these organized behavioral health services, many of these patients would need inpatient psychiatric hospitalization which is not available in this community. Others would not have access to care from the psychiatrist who offers services via the Hospital Department. Our medical staff included no psychiatrists prior to the development of the Department.

The cumulative 20% decrease in payment rates for Group Psychotherapy places real risks that the Hospital will no longer be able to provide Mental Health Services. Salary and benefits costs continue to rise, and these are the primary expenses in the Department. In our small community, we find we often have to offer salary incentives to attract licensed mental health professionals to the area, as these professionals are in short supply in the area and we compete with hospitals in major metropolitan areas for staff.

1301 Wonder World Drive • San Marcos, TX 78666 • Phone 512.353.8979

We urge CMS to re-consider these proposed cuts in order to preserve access for beneficiaries to these needed services.

Sincerely,

Gary L. Jepson
President/CEO

(14)

GACHASSIN

L A W • F I R M

(A LIMITED LIABILITY COMPANY)

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August 23, 2007

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore MD 21244-1850

Re: CMS-1392-P
Proposed Changes Affecting Critical Access Hospitals (CAHs) and Hospital Conditions of Participation (CoPs)

Dear Sir/ Madam:

Several of our clients are CAHs. We offer comments on the following issue:

42 CFR § 485.610(e)(3)

The proposed language to this section reads, "If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in paragraph (e)(1) of this section, by co locating with another hospital or CAH after January 1, 2008, **or creates or acquires a provider-based location** or off-campus distinct part unit after January 1, 2008, that does not meet the requirements in paragraph (e)(2) of this section, the CAH's provider agreement will be subject to termination in accordance with the provisions of § 489.53(a)(3), unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both." [Emphasis added.]

The language bolded is of particular concern because "provider-based location" can be interpreted as being an on-campus unit or clinic, or even a unit utilizing space inside the CAH itself.

Section XVIII of the preamble has language that suggesting this is not the intent. Co-location and off-campus arrangements appear to be the concern.

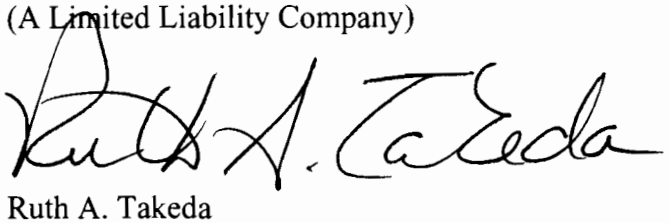
If provider-based locations, even within an existing CAH, will be subject to the geographic or temporal requirements of 42 CFR 482.610(e)(2), it would result in a static existence for CAHs. They would not have the flexibility, even on their own campuses or within their own facilities, to offer any expansion of services for their patient populations after January 1, 2008.

We suggest that the language be clarified, unless it meets the intent of the proposed rule.

Thank you for your review and consideration of these comments. I am

Very truly yours,

GACHASSIN LAW FIRM
(A Limited Liability Company)



Ruth A. Takeda

cc: Chris Kohlenberg, CPA, MBA, MHA, FHFMA
Langlinais Broussard & Kohlenberg

(15)

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
P.O. Box 8010
Baltimore, MD 21244-1850

Georgia Hospital Association
Center for Rural Health

Subject: Comment Letter Re: Necessary Provider CAHs ; CMS-1392-P

To Whom It May Concern:

On behalf of the Center for Rural Health of the Georgia Hospital Association and its 35 Critical Access Hospital members, we offer this letter in opposition to the following portion of the proposed ruling – *Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates.*

While small rural hospitals in Georgia recognize the intent of CMS's clarification of rule §413.62(a)(2), they further recognize the ongoing and compelling need to extend access to health services to residents of rural areas. **The proposed clarification rule imposing the distance requirements on new CAH off site services will limit access to rural citizens in following manner.**

The rule will widen geographic gaps in rural health services.

1. The 35 mile (or 15 in case of mountainous terrain or secondary road) radius requirement is not indicative of overlapping services and/or competing providers. The radius assumes rural residents within 35 miles of another healthcare facility have adequate access to health services. Other circumstances such as locations of employment, types of services available, and availability of transportation often limit access to rural residents within the aforementioned radius. Continuing to apply the "necessary provider" designation to off site services will provide additional access to healthcare for rural residents. Imposition of the radius statute to CAH operated off site facilities will limit access to health services for residents of rural areas.

The rule will result in a reduction of rural physicians.

2. The proposed rule will stifle Critical Access Hospital's ability to recruit and hire physicians in rural service areas. Critical Access Hospital's often only recruitment tool is to employ physicians in off site practices. Elimination of this tool will reduce the number of rural physicians practicing at CAHs thus limit access to direct physician services. Continuing to apply the "necessary provider" designation to off site services will preserve one of the only methods a CAH has to recruit physicians to rural service areas. Imposition of the rule will result in fewer rural physician on the medical staffs of CAHs.

Georgia Hospital Association-Center for Rural Health
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William Witmer, MD, FACC
Fran Wolf, MD, FACC

August 17, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
PO Box 8011
Baltimore, MD 21244-1850

Re: File code CMS-1392-P

To Whom It May Concern:

I am writing in opposition to your change in IVUS related APC codes as proposed by CMS. As a practicing interventional cardiologist in Green Bay, Wisconsin, I utilize IVUS on approximately 15-20% of my cases. Intervascular ultrasound is helpful to me in multiple ways, including deciding whether coronary lesions are significant enough to justify intervention, to better evaluate lesion morphology for picking equipment, and for evaluating whether stents are fully deployed, all of which provide better patient care and result in better outcomes for patients. The reduction in reimbursement for IVUS related procedures will result in the elimination of IVUS as a tool for interventional cardiology. Ultimately, I do believe strongly that this will result in needless interventions, poor patient care, and ultimately more expense. The use of IVUS should be encouraged for better patient care and not discouraged as is being proposed by CMS. I certainly would be more than happy to provide any further explanation as to why I directly and strongly oppose the reduction in IVUS related reimbursement.

I thank you very much for your consideration.

Sincerely,

David W. Mathias, MD

D: 08/17/07 T: 08/21/07
DWM/tt53

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17

August 28, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

The Focused Ultrasound Surgery Foundation (FUSF) is pleased to submit comments in response to the proposed CMS rule for 2008 in reference to the MRgFUS procedure.

The Focused Ultrasound Surgery Foundation was founded as a catalyst to compress the time between technology development and the treatment of patients. The Foundation is a 501(c)(3) not-for-profit organization. The mission of the Focused Ultrasound Surgery Foundation is to shorten the time from technology development to patient treatment, develop new applications and accelerate the worldwide adoption of MR-guided focused ultrasound surgery, which it seeks to accomplish by engaging in a number of "accelerating" activities.

We welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. However we believe that the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

We recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotactic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotactic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized by the hospitals.

It is our firm belief that Focused Ultrasound Surgery offers a revolutionary method of surgery that should be embraced and encouraged as rapidly as possible to maximize its

benefits to society. A steady stream of research data continues to indicate that this treatment offers safety and efficacy rivaling or exceeding the currently available treatment options in a less invasive manner along with a shorter recovery time. By assigning the treatment to an APC that fully covers the necessary aspects of the treatment planning associated with the surgery, the CMS will serve to make this treatment option available to a greater number of patients requiring treatment and provide a precedent for the procedure to be fully covered for other disease vectors including breast, liver, prostate, and brain cancer.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Alexander Crosby, COO

HEART & VASCULAR CARE

(18)

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John A. Stern, MD

August 28, 2007

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

We are concerned that proposed changes to the Skin Repair APCs will negatively affect patient access to regenerative wound care products, particularly Apligraf®. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50 percent from CY 2007 rates. Patient access to this important product is jeopardized by proposed payment changes characteristics of each procedure. We are concerned that the APC classification for Apligraf's CPT procedure codes do not account for the actual clinical resource use in our experience.

We have reviewed our charges for skin repair procedures, and I believe the CY 2006 data available for the proposed rule is unlikely to accurately reflect the true resource costs for applying Apligraf.

We request that CMS place CPT codes 15340 and 15341 into APC 0135 (Level III Skin Repair) to best reflect the actual resource cost of applying Apligraf. This is consistent with other skin substitute products.

Sincerely,

David H. Stubbs, M.D.

DHS/kll

CAPE FEAR VALLEY
TRANSFORMING HEALTHCARE

(19)

August 23, 2007

BEHAVIORAL HEALTH CARE
CAPE FEAR VALLEY MEDICAL CENTER
CAPE FEAR VALLEY REHABILITATION CENTER
HEALTH PAVILION NORTH
HIGHSMITH-RAINEY SPECIALTY HOSPITAL

BLOOD DONOR CENTER
CANCER CENTER
CARELINK
CAPE FEAR VALLEY HOME HEALTH & HOSPICE
CUMBERLAND COUNTY EMS
FAMILY BIRTH CENTER
HEART & VASCULAR CENTER
HEALTHPLEX
LIFELINK CRITICAL CARE TRANSPORT
PRIMARY CARE PRACTICES
SLEEP CENTER

Mr. Kerry Weems
Administrator, Centers for Medicare & Medicaid Services

Department of Health and Human Services
Attention: CMS–1392–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

ATTN: CMS-1392-P

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **Skin Repair Procedures**

Dear Administrator Weems:

Cape Fear Valley Health System appreciates this opportunity to comment on the Hospital Outpatient Prospective Payment System proposed rule for calendar year 2008. Our comment addresses Medicare payment for Skin Repair Procedures performed as hospital outpatient services. Cape Fear Valley Health System is a leading wound care center and treats Medicare beneficiaries for diabetic foot and venous leg ulcers.

Apligraf is a unique human skin substitute for diabetics and others who suffer from chronic ulcers. Our clinicians use Apligraf to improve the quality of care for diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Treatment with Apligraf and other skin substitutes can avoid limb amputations in many of these patients. The Proposed Rule would drop the CY 2008 payment amount for Apligraf to $132.82 — a decrease of greater than 50% from CY 2007 rates.

In the Proposed Rule, CMS proposes replacing the four existing skin repair APCs with five new APCs in order to improve resource homogeneity and clinical homogeneity. CMS stated its intent to redistribute each of the existing skin repair procedures into the five proposed APCs, taking into account the frequency, resource utilization, and clinical characteristics of each procedure.

Thank you for this opportunity to comment. If you would like to discuss this issue further, please contact Lucas Henry at (910) 609-7168.

Sincerely,

Lucas Henry, PT
Acute Care and Wound Care Supervisor
Occupational and Physical Therapy

Lake Medical Imaging & Vascular Institute

20

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RADIOLOGISTS AT:
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The Villages Regional Hospital

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VISIT US ON THE WEB:
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lakevascular.com

August 23, 2007

Re: Docket #CMS-1392-P (Proposed Changes to HOPPS)

Dear Committee Members:

We are Managing Physicians with Lake Medical Imaging, which encompasses three outpatient diagnostic imaging centers serving Central Florida for 35 years. We are writing to express concern with regard to Medicare's proposed payment for FDG PET procedures under the Hospital Outpatient Prospective Payment System for Calendar Year 2008. Lake Medical Imaging has been providing Positron Emission Tomography services since early 2003.

We appreciate the hard work and careful consideration CMS put into developing the proposed rule and are aware of the rate and payment method for PET services that CMS has set forth in the Federal Register. In response to the agency's request for public comments on this issue, we would like to urge CMS to retain current Medicare payment for these critical services as a separate payment for the radiopharmaceutical and for the technical component. The proposed payment reductions for PET radiopharmaceuticals will have limiting effects on beneficiary access to PET services.

Proposed bundling of RP into the technical payment would drastically reduce the reimbursement rate for PET scans for patients with cancer and these reductions would significantly diminish access to PET for Medicare patients. We are very concerned that our PET program simply cannot sustain such a substantial reduction in Medicare payment again in a single year and still continue to provide high quality services. The potential result would be a significant reduction in access to PET for Medicare beneficiaries.

PET Imaging has the unique ability to provide physicians with information about the body's chemistry, cell function, and location of disease can eliminate unnecessary surgeries, reduce the number of diagnostic procedures and otherwise demonstrate to physicians the most effective mode of treatment.

The clinical benefits of this technology are enormous, as are the costs of continuing to offer this service, including the medical equipment (the lease is $270K for a PET scanner, in addition to a $180K+ maintenance contract) and highly trained and specialized staff (two technologists and one aide at $150K per year). The radiopharmaceutical FDG cost $155 per dose, has a very short half-life and PET centers need to purchase sufficient quantities to administer to patients. Medicare cut our reimbursement by **46%** this year: the highest reduction to any modality. It costs approximately $822 per PET/CT, noninclusive of radiologists' time and other operating costs. The proposed bundling of RP into the technical component would represent a significant decrease in total reimbursement for FDG PET, making it very difficult to realize a profit.

Thank you for your consideration; we appreciate the opportunity to submit and discuss these comments with you.

Sincerely yours,

MICHAEL S. LEVINE, M.D.
Senior Partner

CATHRINE E. KELLER, M.D
Managing Physician.

Board Certified Radiologists

Michael S. Levine, MD
Marc S. Schwartzberg, MD
Mahrad Paymani, MD
Rosendo Diaz, MD
Cathrine E. Keller, MD
Manoj Bhatia, MD
Jon E. Anderson, MD
C. Steve Houston, MD
Joseph S. Gurinsky, MD
Mark D. Jacobson, MD
Maurice P. Yoskin, MD
Yi Liu, MD, PhD
David C. Weyn, MD
George E. Kainz, MD
Pairoj S. Chang, MD, PhD
Richard K. Held, MD

Date 08-28-07

(21)

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

I am Dr Thomas Simopoulos and I direct and practice interventional pain management at Boston's Beth Israel Deaconess medical center, an affiliate of Harvard Medical School. I have used spinal cord stimulation and peripheral nerve stimulation for years to control debilitating neuropathic pain for many patients who do not find relief by more simple modalities. Over the years spinal cord stimulation and peripheral nerve stimulation have become increasingly more sophisticated and can more reliably control any given individual's pain for many years. The most impressive advancement in recent times is the rechargeable battery. Rechargeability has done much to improve patient care. Patients with stimulators no longer have to worry about battery depletion. Rechargeable batteries provide more programming options and that means better pain control for patients. Finally rechargeable batteries reduce the need for surgery because batteries are no longer depleted and can be recharged transcutaneously. The reduction in surgery means less risk on infectious complications. There is less morbidity and reduced healthcare costs over time. In my practice all of there positive effects are being realized as we are approaching 3 years in a number of my patients and I have not needed to surgically replace batteries.

As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare's hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated "substantial clinical improvement" and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94—thousands less than the average cost of rechargeable neurostimulators—will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS' own data shows the median cost for implanting rechargeable neurostimulators is $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

The loss of rechargeable stimulators will be detrimental to pain control. Conventional batteries cannot meet the needs of chronic pain patients. Rechargeable systems have also reduced the needs for long-term morphine pumps. The impact of rechargeable systems can be summarized as follows:

- Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.
- The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.
- Rechargeable batteries reduce the number of stimulator explants because of long-term dissatisfaction.
- Rechargeable systems reduce the need for additional surgery and morphine pumps. They also reduce the associated complications of surgery by avoiding surgery.

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population

indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

I appreciate CMS's past recognition of the clinical benefits offered by rechargeable technology for Medicare beneficiaries, and I hope that you will carefully consider these comments. Should you have any questions or need additional information, please feel free to contact me at [insert contact information].

Sincerely,

Thomas T Simopoulos MD
Director of Interventional Pain Services
Beth Israel Deaconess Medical Center
Boston, MA 02215

Washington University in St. Louis

SCHOOL OF MEDICINE

Department of Radiation Oncology

22

Electronically submitted comment

August 30, 2007

Herb B. Kuhn, Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS proposed changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Director Kuhn:

Our hospital wishes to thank CMS for the opportunity to provide appropriate comments in response to the proposed 2008 Hospital Outpatient Prospective Payment System and 2008 Payment rates released by CMS on July 16, 2007.

We wish to address the CMS APC assignment for a new technology made effective in program transmittal 1259 dated June 1, 2007. A new technology assignment was approved by CMS specific to the Implantation of the DVS Dosimeter for treatment of cancer patients.

We appreciate that CMS has correctly determined that this technology is new and requires the development of a new APC assignment; however, CMS has made a significant error in the APC assignment for this new procedure and technology.

The new technology code (**C9728**) approved by CMS should include the cost of the implant procedure as well as the DVS sensors. The code assignment made has excluded the cost of the sensors and only accounts for the cost of the implant procedure. In addition, the existing code for implantation into the prostate (**55876**) also excludes the cost of the DVS sensors.

It is our understanding that the purpose of the new technology APC application is to permit hospitals to utilize new technology appropriately to provide care for beneficiaries, and to provide the hospitals a mechanism for reimbursement of new technology. The APC assignments for C9728 and 55876 do not account for the cost of the DVS technology, and the proposed 2008 HOPPS payment system does not offer a mechanism for reporting the DVS technology cost.

We encourage CMS to develop a code that will permit hospitals to report the cost of the technology associated with these two procedures so that cancer patients may have access to this new technology as CMS intended under the APC new technology process.

Thank you in advance for your time and consideration for this important clinical and hospital reimbursement issue.

Sincerely,

Jeff M. Michalski, M.D.
Professor and Clinical Director

cc: Carol M. Bazell, M.D., Director, Division of Outpatient Care (***Carol.Bazell@cms.hhs.gov***)

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MERCY CANCER CENTER
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23

Aug 30, 2007

Herb Kuhn - Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule; CMS-1392-P

Dear Mr. Kuhn:

In reading the proposed rule changes for 2008 we have concern over the packaging of "Guidance Services", in particular the impact that will have on radiation oncology. The Summary states that

"Therefore, by proposing to package payment for all forms of guidance, CMS is specifically encouraging hospitals to utilize the most cost-effective and clinically advantageous method of guidance that is appropriate in each situation by providing them with the maximum flexibility associated with a single payment for the independent procedure."

While there needs to be a great deal of flexibility left to the clinical staff we are concerned that this new flexibility will lead to a reduction in utilization of new clinically significant but capitally intensive procedures. Guidance procedures are not fully integrated in all radiation oncology centers and eliminating the financial incentive to acquire this expensive equipment will deter centers from properly implementing image-guided technology. The CMS Summary states "CMS did not consider resource cost when proposing to package guidance procedures." Also, additional staff and resources are required to perform the highly technical image guided radiotherapy and without a financial incentive to perform these tasks, fiscally justifying the additional staff will be impossible.

Assuming some form of image guidance is performed on most IMRT treatments then the increase in IMRT reimbursement should compensate for the loss of the guidance codes, but it does not. In 2007, a typical IMRT prostate treatment (77418) with implanted gold fiducial markers and a set up using stereoscopic guidance (77421) would have yielded a $403.87 payment. In 2008 the proposed rule would net a payment of only $364.80, a reduction in total reimbursement of nearly 10%. It is not clear how a 10% reduction in payment will "encourage hospitals to utilize the most... clinically advantageous method of guidance".

Image guided radiotherapy allows clinicians to treat lesions in a way they never have before. Daily CT information to evaluate treatment response, precise localization to spare healthy tissue and the ability to treat lesions that would otherwise be impossible make image guidance essential to the future of cancer care. Eliminating the image-guided codes would slow the implementation of these advanced technologies while limiting staff and utilization.

MERCY CANCER CENTER
A department of Mercy Medical Center-North Iowa
Member, North Central Cancer Treatment Group

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We ask that CMS delay the 2008 packaging proposal until a more thorough investigation into the integration of essential image guidance technology into the community based cancer center is performed and made public. I also recommend that CMS evaluate the effect of the decreased reimbursement with the bundling of the guidance codes and its effects on technology integration and traditional staffing levels.

Sincerely,

Blake Dirksen, MS	Kandice Nedved	Tami Fitzgerald	Dr. Timothy McKone	Dr. James Simon
Medical Physicist	*Cancer Center Director*	*Patient Representative*	*Radiation Oncologist*	*Radiation Oncologist*

J. MICHAEL STANTON, D.O., F.A.O.C.A.
Diplomate, American Osteopathic Board of Anesthesiology
Diplomate, American Academy of Pain Management

LEROY GILLAN, C.R.N.A., C.H., M.P.H.

RAFAEL RODRIGUEZ, P.A.-C.
National Commission on Certification of Physician Assistants

PATRICK K. STANTON, D.O.
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SUE BIDDY, F.N.P.-C.
Certified, American Academy of Nurse Practitioners

FREDERICK ORITI, P.A.-C.
National Commission on Certification of Physician Assistants

24

August 28, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates

Issue Identifier: Implantation of Spinal Neurostimulators

Dear Sir or Madam:

As a Board Certified Anesthesiologist specializing in pain management, I implant numerous spinal neurostimulators on an annual basis. As you know, rechargeable neurostimulators have received transitional pass-through payment under Medicare's hospital outpatient prospective payment system (OPPS) since January 1, 2006, and their pass-through status will expire on January 1, 2008. Transitional pass-through payment was granted to rechargeable neurostimulators on the basis that these devices demonstrated "substantial clinical improvement" and that the technology would be inadequately paid under APC 0222, to which implantation of neurostimulator devices is assigned. Pass-through payment made rechargeable technology available to patients in the hospital outpatient setting. Without pass-through payments, many facilities would have found rechargeable neurostimulators too costly to implant, which would deny patients and CMS itself (in the form of long-term savings) the benefits of these devices.

With neurostimulators coming off pass-through status for CY 2008, CMS is proposing to retain the implantation of both rechargeable and non-rechargeable neurostimulators in APC 0222, despite very significant differences in the cost of the two devices. I am concerned that the proposed payment for APC 0222 of $12,313.94—thousands less than the average cost of rechargeable neurostimulators—will create a strong financial disincentive for the use of rechargeable neurostimulators. CMS' own data shows the median cost for implanting rechargeable neurostimulators at $18,088.71, while the median cost for non-rechargeable neurostimulators is $11,607.75, a difference of $6,480.96.

The development of rechargeable neurostimulators represents a substantial advancement over non-rechargeable neurostimulators. A few examples of why rechargeable stimulators are better for patients is as follows:

- ***Chronic pain patients requiring higher power needs to achieve pain relief can use their rechargeable system without concern for premature battery depletion.***
- ***The increased battery life of rechargeable neurostimulators results in a reduction in the number of device replacement surgeries and other associated medical interventions. The reduced number of surgeries and other medical interventions results in less patient trauma and a substantial cost savings to the healthcare system over time.***
- ***Rechargeable neurostimulators allow unparalleled programmability.***
- ***The ability to recharge the battery allows the patient to utilize up to 16 electrodes which covers a larger pain pattern for such patient.***

I am urging CMS to create separate APCs for the implantation of rechargeable and non-rechargeable neurostimulators, which should adequately recognize the cost of both devices and allow the patient population indicated for rechargeable neurostimulators continued access under the hospital outpatient prospective payment system.

I appreciate CMS's past recognition of the clinical benefits offered by rechargeable technology for Medicare beneficiaries, and I hope that you will carefully consider these comments. Should you have any questions or need additional information, please feel free to contact me at [insert contact information].

Sincerely,

J. Michael Stanton, DO, FAOCA

INOVA ALEXANDRIA
HOSPITAL

125

4320 Seminary Road
Alexandria, Virginia 22304
Tel 703 504-3000

August 21, 2007

Herb Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Rule; CMS-1392-P

Dear Mr. Kuhn:

The Inova Health System, is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 2, 2007 *Federal Register* notice regarding the 2008 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

Inova Health System Cancer Center's:
The Inova Alexandria Hospital Cancer Center, located in Alexandria Virginia, provides a full spectrum of cancer care and was one of the first in the area to offer radioactive seed implants for treating prostate cancer. The department treats approximately eighty patients a day.

U.S. News & World Report has ranked the Inova Fairfax Hospital Cancer Center, located in Falls Church, Virginia, as one of the top cancer centers in the United States. Since 1968, it has retained continuous accreditation as a teaching hospital/cancer program. The center treats approximately one hundred twenty patients a day.

The American College of Surgeons Commission on Cancer (ACoS) accredits both Inova Alexandria Hospital and Inova Fairfax Hospital Cancer Center's with full commendation.

General Comments and Recommendations:
We would like to thank CMS for significant positive changes in radiation oncology payment policy since the inception of HOPPS. However, we are extremely concerned that CMS has proposed significant changes to their packaging approach without providing the relevant data for public review and comment during this 60-day comment period.

The Inova Health System recommends that CMS delay the 2008 packaging proposal until complete information is made available to the public and stakeholders have the opportunity to fully comment.

Specific Comments and Recommendations:
For 2008, CMS is proposing to package payment for items and services in seven categories of supportive ancillary services into the payment for primary diagnostic or therapeutic modality with which they are performed:

- Guidance services
- Image processing services
- Intraoperative services
- Imaging supervision and interpretation services

- Diagnostic radiopharmaceuticals
- Contrast agents
- Observation services

The proposed methodology to determine payment for packaged services is not transparent and may lead to inappropriate reimbursement for image guidance services. Based on the limited information available to us at this time, we are very concerned that the proposed reimbursement structure may hinder hospitals from their ability to invest in advanced technologies. This would impact the daily patient localization in a way that could have a direct negative impact on the quality of patient care.

Recently, Inova Health System made a commitment to purchase two versatile high powered linear accelerators, called Trilogy, which offer ultraprecise radiation treatment. These multifunctional linear accelerators, with a full complement of accessories and software, can deliver many forms of radiation therapy, including conventional, 3D conformal, IMRT, IGRT, stereotactic radiotherapy and radiosurgery. These powerful tools allow oncologists to offer patients personalized cancer care encompassing the most optimal treatment for each individual case. The Trilogy system offers advanced treatment for more patients as well as reduced treatment times. Trilogy was a very expensive commitment for Inova Health Systems and the cost of the equipment including the construction, millwork, etc. was over $7,000,000. A four year service contract for both Trilogies is $1,500,000 of which we could not reasonably commit to, if we cannot get reimbursed for image guidance services.

CMS should make all relevant data associated with the packaging proposal available to the public on the CMS Web-site. Given that the packaging proposal data is not available for public review and comment, CMS should postpone their 2008 packaging proposal.

The Inova Health System recommends that CMS delay the 2008 packaging proposal until complete information is made available to the public and the stakeholders have the opportunity to fully comment.

Appropriate payment for radiation oncology procedures is necessary to ensure that Medicare beneficiaries will continue to have full access to high quality cancer treatment in the hospital outpatient setting. We encourage CMS to consider this issue during the development of the 2008 HOPPS Final Rule.

Sincerely,

Mr. Rod Huebbers, Executive Vice President,
Inova Health System &
Interim Chief Executive Officer
Inova Alexandria Hospital

CC: Roslyne Schulman, American Hospital Association

A I
P M
Advanced Interventional
Pain Management, PA

(26)

August 15, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-P
P.O. Box 8011
Baltimore, MD 24244-1850

Dear Sir and Madam:

I am a pain management physician in North Carolina. I have been treating patients with chronic pain for 18 years. Part of my practice involves the placement of neurostimulators for chronic intractable pain. I am writing specifically about the lack of differential reimbursement regarding for hospitals regarding the use of rechargeable versus non-rechargeable generators. The rechargeable generators are in fact more expensive at the initial investment, however, their projected life is significantly longer than the equivilant of the non-rechargeable devices. Further more when the non-rechargeable devices are depleted, the patient will have to undergo a second surgery to have a new generator placed. Given that the typical rechargeability persists for the rechargeable devices on the market for typically 5-7 years, I would estimate that CMS would end up buying two non-rechargeable devices and paying for two surgeries during the course of the life of one rechargeable generator which would need only one surgery and only need to be purchased once. Given that the non-rechargeable devices are not half the cost but more roughly 75%, this will be an increase in spending for CMS services. This economic analysis discounts the associated morbidity and potential mortality associated with reoperation.

Respectfully,

T. Stuart Meloy, M.D.
Advanced Interventional Pain Management, P.A.

TSM:sr

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August 30, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1392-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

Stoughton Hospital located within Stoughton, WI, a City of 13,000 residents has served the communities of Stoughton, Oregon, Evansville, and McFarland for 103 years. Our combined service area is comprised of approximately 55,000 residents. We are a sole community Hospital; there are no other hospitals located within the other service area communities. In October, 2004, Stoughton Hospital became a necessary provider Critical Access Hospital with a distinct geri psych unit.

Since 2001, Stoughton Hospital has operated a rehabilitation/sports medicine satellite outpatient clinic within the neighboring service area community of Oregon, WI. As a lessee tenant, we have moved the program two times due to phenomenal growth and demand for these services in that community.

In April, 2007, the Hospital Governing Board approved the Hospital leasing life/safety improved expanded new Rehabilitation facilities within the community of Oregon, a relocation of approximately two (2) miles from the present clinic site. An urgent care service will be added within the facility due to lack of this service in the community and strong community demand for the same. Formal lease contract documents were signed May 14, 2007. The construction plans were reviewed and approved by Mr. Lynn Wallace, State of Wisconsin, Bureau of Health Services, Division of Quality Assurance (State and Federal life safety engineer). Construction is currently underway with completion anticipated April, 2008 per contract.

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Affiliated with SSM Health Care of Wisconsin

In view of above developments, Stoughton Hospital is seriously concerned about the recently proposed CMS rule 42 CFR 485.610 (e) that appears to restrict Critical Access Hospitals from creating, acquiring or relocating outpatient satellite centers within our service area after January 1, 2008. Obviously, Stoughton Hospital must insist and has demonstrated the Hospital has "created and acquired" the Oregon satellite operation by virtue of its ongoing six (6) years operations there and signed lease contract obligation for an improved replacement facility currently under construction that precedes the date of proposed rule posting.

We request clarification and exemption for our Oregon rehabilitation/urgent care project from the proposed rule January 1, 2008 restriction based on facts and merits of our request.

Sincerely,

Terrence Brenny
President/CEO
Stoughton Hospital

RE: Implantation of Spinal Neurostimulators

(28)

Matt Sloan, M.D.
2692 W. Walnut Street, Suite 203
Garland, TX 75042
(469) 326-0014

To Whom It May Concern,

I have recently started utilizing spinal cord stimulators in my practice in order to assist in controlling chronic neuropathic pain. I am familiar with this technology from the past. I feel the technological changes, especially the rechargeability, in the last few years have been instrumental in improving the care of my patients.

Rechargeable neurostimulators are crucial for my patients. In the past, patients have to undergo another surgical procedure upon discharge, which could be as short as a few months. Many of my clientele aren't physically able to undergo or want to avoid multiple surgeries, which is why I recommend this procedure with a rechargeable system. I also feel this technology financially makes good sense for my patient, the hospital, and especially the insurance. They will all benefit from not paying for multiple procedures due to depletion of the battery.

It has come to my understanding that the creation of a new payment category for rechargeable neurostimulators to cover the cost of this technology is being reviewed. Having the reimbursement to compensate for the appropriate cost difference will be crucial in allowing this technology in the hospital. I fear if this proper reimbursement is not established that I will not be able to provide this to my patients. Again, having a rechargeable system is important for an overall cost savings to the patient, hospital, and insurance. It will greatly impact my patients to have a rechargeable system thus avoiding unnecessary replacement surgery.

Please feel free to contact me if you have any additional questions or needed information in order to assist with the creation of a new payment category for rechargeable neurostimulators.

Thank you for your time and attention.

Sincerely,

MD

Matt Sloan, M.D.

CATHOLIC HEALTH INITIATIVES

St. Francis
Medical Center

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: 2008 OPPS Packaged Services
File Code CMS-1392-P

To Whom It May Concern:

Our facility, Saint Francis Medical Center, has numerous concerns regarding the proposed rule for the 2008 outpatient prospective payment system (OPPS). As proposed, several radiological diagnostic and therapeutic imaging, cardiac image-guided invasive, and electrophysiology (EP) procedures, as well as contrast agents and radiopharmaceuticals, will be packaged into payment for an "independent service."

We are concerned that certain designated "dependent" procedural services may or *may not* always be performed and coded as presented and assumed in the proposed rules, We understand that not all providers have reported data elements accurately for these procedures, radiopharmaceuticals and contrast agents. Therefore, CMS may not be informed appropriately regarding likely coding scenarios for many of these proposed packaged services and items. Therefore, we offer the following example and reason as to why these services should not be packaged as proposed. This is just one example.

71090 Fluoroscopic guidance for pacemaker insertion

Fluoroscopic guidance is not always utilized for pacemaker and cardioverter-defibrillator (ICD) insertions; especially when only the generator device is inserted or replaced. The additional equipment and resources should be recognized and separately reimbursed when provided (as they are currently).

Saint Francis Medical Center performs approximately 75 cardiac pacemakers and replacement procedures per year. Because of the continuous reduction in payment, especially for outpatient claims, bundling this payment continues to negatively impact our cardiology program. The cost of these expensive, yet life-saving, devices for a growing senior and middle-aged population is barely covered, if at all, by current APC

payment. Current payment does not address the sophisticated equipment and skilled medical personnel and other overhead expenses necessary to perform these interventions.

Our cost (including both direct and indirect) for these procedures are $9026.00 and our reimbursement is $9167.00.
We respectfully request reconsideration of the packaging of the potential radiological service 71090. We also request that you review the current proposed payment for pacemakers and replacements.

As stated above, in your final analysis, please consider that procedural services may or may not "always" be performed and coded as you have presented in the proposed rule. Coding methods for many of these proposed packaged services may vary from those that you have assumed.

Thank you for your consideration.

Sincerely,

Karen Riva RRT, RN, MHAL
Director of Cardiology Services
Saint Francis Medical Center
Grand Island, NE 68802

Hennepin County Medical Center
HCMC
Level 1 Trauma Center

Internal Medicine

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30

Cardiology Division

Richard W. Asinger, M.D.
Director

Woubeshet Ayenew, M.D.
Bradley A. Bart, M.D.
Fouad A. Bachour, M.D.
Steven R. Goldsmith, M.D.
Marco A. Guerrero, M.D.
Charles A. Herzog, M.D.
James N. Mohn, M.D.
Richard D. Taylor, M.D.
Valerie K. Ulstad, M.D.
Kyuhyun Wang, M.D.

August 31, 2007

Leslie V. Norwalk, Esq.
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Ms. Norwalk:

I am the medical director of the echocardiography laboratory at Hennepin County Medical Center in Minneapolis, Minnesota. I supervise an ICAEL-accredited laboratory and have had a primary clinical and research interest in echocardiography during my 23 years as an attending cardiologist at Hennepin County Medical Center. My major interest in clinical research focuses on heart disease and end stage renal disease (ESRD). Our clinical laboratory has performed stress echocardiography for more than 15 years; the one primary focus for which the laboratory was established was to perform non-invasive evaluation of patients with end stage renal disease for cardiac screening before elective renal transplant. Besides serving as the medical director of the cardiac ultrasound laboratory at Hennepin County Medical Center and attending cardiologist, I am also a professor of medicine at the University of Minnesota. My research appointment is director of the Cardiovascular Special Studies Center of the United States Renal Data System.

I have recently learned that CMS is proposing to eliminate separate payments for echo contrast agents (eg; Definity, also known as perflutren). Under this proposal, reimbursement would be identical whether or not a contrast agent for left ventricular opacification is viewed. In my roll as echo lab director, I have personally interpreted more than 30,000 echocardiographic studies. Reflecting our special clinical and

research interest, we have also performed more Dobutamine stress echocardiograms in patients with end stage renal disease than any other clinical laboratory in the world. As lab director, I have found that echo contrast agents used for LV opacification play a key clinical role in increasing diagnostic accuracy of assessment of global or regional systolic performance of the left ventricle in patients with difficult imaging. This particularly applies to patients with end stage renal disease (who frequently have severe concentric left ventricular hypertrophy and small LV volumes). Stress imaging can be very challenging in this patient population and the use of echo contrast has served to markedly improve the level of non-invasive imaging (and attendant quality of care) for patients with difficult imaging, of whom ESRD patients are a good example.

Our medical center is a safety net hospital and we serve an underserved population. We also have a disproportionately large number of patients with end stage renal disease cared for at our hospital both in the inpatient and outpatient setting. If the CMS proposal to eliminate separate payment for echo contrast agents were finalized, our patient population would no longer have ready access to echo contrast agents and thus would obtain inferior cardiology care in my opinion. We have reviewed our recent contrast expenditures, and we project a cost of approximately $300,000 a year contributable to contrast agents in our echo lab. If CMS were to eliminate separate reimbursement for echo contrast agents, Hennepin County Medical Center would not be able to continue to provide contrast agents to patients without reimbursement as we project our annual cost to be approximately $300,000 a year.

In summary, the CMS proposal to eliminate separate payments for echo contrast agents represents a serious threat to patient care and I strongly advise that this proposal be rejected. I would be happy to further discuss this issue with CMS representatives.

Sincerely,

Charles A Herzog, M.D., F.A.C.C.
Director Echocardiography Laboratory, Hennepin County Medical Center
Director, Cardiovascular Special Studies Center, United States Data Renal System
Professor of Medicine, University of Minnesota

Lisa Wasemiller-Smith, M.D., F.A.C.O.G.
A Professional Corporation
Obstetrics & Gynecology

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September 7, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1392-P(Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Kuhn:

As a practicing gynecologist I am pleased that the CMS has offered the opportunity to comment on the proposed rule regarding changes to the Medicare hospital outpatient prospective payment system for calendar year 2007.

MR guided Focused Ultrasound (MRgFUS) has the potential to revolutionize surgery as we know it today and I am proud to be among the leading physicians offering this technology to patients. We believe that this technology has tremendous potential to improve health outcomes and the uterine fibroid application is only the first of many to come.

I welcome CMS' proposal to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a proposed payment of $3,918.43 and the recognition that it belongs with other image guided therapies. It shares many similarities with these procedures both clinically and in terms of resources required:

1) Treatment objective is non-invasive tumor destruction
2) The surgery is conducted using an external source of energy which penetrates into the body to reach the tumor
3) Imaging technology is required
4) Extensive treatment planning is involved with continuous monitoring during treatment

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5) Expensive capital equipment in dedicated specialized treatment rooms
6) Lengthy procedure time ranging from 2-5 hours

However the payment rate for this procedure continues to be far below the costs incurred to provide this service and does not reflect the treatment planning component that is required to perform the MRgFUS procedure.

I recommend that CMS consider assignment of 0071T and 0072T to APC 0127, Level IV Stereotatic Radiosurgery, which would permit appropriate payment for the extensive treatment planning. Level IV Stereotatic Radiosurgery assignment would permit MRgFUS to be classified into an APC with similar clinical and resource homogeneity.

The MRgFUS procedure provides excellent clinical results in a cost effective manner and should be assigned to an appropriate APC that permits hospitals and outpatient centers to offer this less invasive procedure option to patients with uterine fibroids. We urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 which more accurately reflects the clinical and economic resources utilized.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Lisa Waseniller-Smith, M.D.

LWS/zrh

(32)

MED-EL
Medical Electronics

September 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1392-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: [CMS-1392-P] Medicare and Medicaid Program; CY 2008 Proposed Changes: Proposed Rule

Dear Sir or Madam:

MedEl Corporation is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1]

MedEl Corporation is encouraged with the proposed increased payment rates for the cochlear implant and related services. However, the proposed payment is still significantly less than the hospital's cost to provide the device and associated services. We are providing comments on issues that pertain to sections: OPPS: Device-Dependent APCs and APC Relative Weights.

RE: OPPS: Device-Dependent APCs

While the proposed CY2008 payment for the cochlear implantation (APC 0259 – Level VI ENT Procedures) is increasing, it includes payment for services that currently receive separate reimbursement (e.g. 95920 – intraoperative nerve test). When the packaged services effect is taken into account, the 2008 proposed APC payment level of $25,753.49 is still significantly less than the average cost of $31,988.81[2] for the hospital to acquire the cochlear implant and the associated costs to provide the implantation service.

The proposed 2008 regulations indicate a change to the median cost calculation for device-dependent APCs. Thank you for this proposal to refine this method and we are in agreement with your proposal as it applies to the rate setting for CY2009 year and forward. However, for the CY2008 rate year, we believe there should be an adjustment to the calculation as it pertains to the FB modifier. During the 2006 claim year, the FB modifier was used only when a device was provided at no cost. Therefore, the data pool used to determine the median cost of the 2006 data likely includes claims for devices provided at a reduced cost or for which the hospital received credit. While the number of these claims may be small, they are significant because of their power to lower the median cost used to calculate the 2008 payment rates.

[1] 72 Federal Register 42628 (Aug. 2, 2007).
[2] Average hospital invoice device cost of $24,342 plus $6,328 for hospital implant services adjusted by 4.3% CPI increase in medical care costs for the 12-months ending July 2007. Costs estimated using the 2006 Lewin Group Analysis (see footnote 4) and industry comments to the CY2007 proposed rule.

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Recommendations and CMS Actions Requested

- We recommend CMS redefine the "token charge" criteria for the CY2008 rate year only to take into account any device provided at a reduced cost. As the definition of "token charge" applies to APC 0259, we recommend defining it to be when the "device charge is in excess of $25,388 (the average "hospital invoice price" of $24,342 detailed in the September 28, 2006 The Lewin Group analysis[3] adjusted by a 4.3% increase in CPI for all Urban Consumers[4]). While this recommendation will make the data pool smaller, it should also more accurately reflect the hospital's cost to provide a cochlear implant. We believe the modification to the FB modifier definition implemented 1/1/2007 will solve this data anomaly for future OPPS rate setting.

- We recommend CMS use the external data developed by The Lewin Group in 2006 and provided in last year's comments to the proposed CY2007 payment rates and adjust the costs using the U.S. Department of Labor's Bureau of Labor Statistics reported Consumer Price Index of a 4.3% increase to all urban consumers for medical care[5].

RE: APC Relative Weights

Proposed Calculation of CCRs

MedEl Corporation appreciates CMS' commitment to address issues related to payment rate accuracy, however, problems with the claims data and the methods used by CMS to set payment rates under OPPS continue to result in inadequate payment rates for a number of procedures utilizing advanced technologies.[6,7] Payment rate inaccuracies continue under OPPS because the methods to calculate relative payment weights do not recognize or adequately adjust for charge compression, a hospital's practice of applying a lower percentage markup to higher cost items and services. The RTI study, commissioned by CMS, confirmed that charge compression introduces a systematic bias into payment rates and recommended short, medium, and long-term interventions to substantially reduce this bias. Specifically, RTI recommended using regression-based estimates to disaggregate the departmental CCR for medical supplies to improve payment rate accuracy.

RTI's recommendations will improve OPPS payment rate accuracy

In the proposed rule, CMS concluded that the OPPS rate setting methodology is already more specific than RTI's recommendation. However, the use of more cost centers or hospital-specific cost centers does **not** equate to more specific rate setting. Implementation of RTI's recommendations will lead to improvements over the current method because RTI's methodology 1) ensures cost centers are designed to reduce markup variation and 2) uses regression-based estimates to adjust, or disaggregate, existing departmental CCRs. Below is a detailed example of how RTI's recommendation will improve OPPS rate setting.

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[3] *Evaluation of the Effect of Charge Compression on Proposed FY2007 Medicare Payment Rates for Cochlear Implantation Devices/Systems.* The Lewin Group, Inc. September 28,2006.

[4] July 2007 Consumer Price Index News Release: http://www.bls.gov/news.release/pdf/cpi.pdf

[5] July 2007 Consumer Price Index News Release: http://www.bls.gov/news.release/pdf/cpi.pdf

6 GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf

7 The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003

The OPPS currently has two cost centers for medical supplies: cost center 5500 (Med Supplies Charged to Patient) and cost center 3540 (Prosthetic Devices), but the cost centers are not designed to reduce markup variation. In the OPPS, revenue code 278 (Other implants) currently cross walks to cost center 5500, which is the cost center representing lower-cost medical supplies. However, using RTI's recommendations as guidance, Revenue code 278 should instead crosswalk to cost center 3540, which represents higher-cost medical technologies. This improvement in cost center alignment will dramatically improve the variation in mark-ups with each cost center. RTI's recommendation then uses the CCRs for these disaggregated cost centers, and not departmental CCRs, for rate setting. Both the proper alignment of cost centers and the use of disaggregated CCRs are necessary for the OPPS to reduce the systematic bias introduced through charge compression.

CMS should take steps to reduce the impact of charge compression for CY 2008

CMS also proposed the development of an all-charges model, using both outpatient and inpatient claims, to evaluate the RTI's recommendation. While we are encouraged that CMS continues to evaluate this issue, it is important for CMS to implement short-term adjustments to this known payment rate accuracy issue for CY 2008 while, at the same time, CMS further investigates longer term solutions. An adjustment or correction to charge compression has been discussed since 2000, yet the underlying claims data and rate setting mechanisms continue to be inaccurate. Applying either the inpatient disaggregated CCRs or using outpatient intradepartmental CCRs, i.e., one CCR for cost center 5500 (Med Supplies Charged to Patient) and a separate CCR for cost center 3540 (Prosthetic Devices), would be a step in the right direction even if an all-charges model were to be implemented at a later date. RTI's recommendation for disaggregating the CCR for devices and implants from the CCR for other supplies improves the accuracy of CMS data, reduces the systematic payment rate bias from charge compression, and can be executed in a simple and concise manner using CMS's own data files.

If CMS is convinced that an all-charges model needs to be developed before implementing RTI's recommendations, we would request that CMS develop a joint OPPS and IPPS task force to ensure that all possible issues, i.e., all-charges model, MS-DRG interactions, potential HSRV impact, etc. are analyzed in time for implementation in the inpatient and outpatient proposed rules for 2009.

Recommendations and CMS Actions Requested

- CMS should apply RTI's recommendations in CY 2008 by either applying the inpatient disaggregated CCRs or using outpatient, regression-based intradepartmental CCRs to calculate OPPS payment rates.

- If CMS deems that implementing RTI's recommendations in the outpatient setting is not feasible for CY 2008, CMS should develop a joint OPPS and IPPS task force to ensure an all-charges model is analyzed and implemented in the inpatient and outpatient setting for 2009.

RE: Revisions to the ASC Payment System APC Relative Weights

In general, MedEl Corporation is encouraged with the increased reimbursement in the ASC setting and preserving the cochlear implant device costs in the ASC payment structure. This payment package should decrease billing and reimbursement errors while simplifying claims filing and processing.

However, as with the comments on the 2008 proposed OPPS, MedEl Corporation believes the proposed ASC payment of $22,839 is insufficient to cover the true costs associated of the cochlear implant and related surgical procedure, and encourages CMS to continue to monitor and adjust payments for cochlear implant claims (69930) paired with L8614 in the ASC and OPPS environments.

In general, we believe the ASC is an important option for well-qualified clinicians and their patients. MedEl Corporation does not recommend the ASC for cochlear implants because reimbursement has improved, but rather because it is a viable option for select patients based on their surgeon's clinical judgment and recommendation.

In conclusion, MedEl Corporation appreciates the opportunity to comment on this important CMS proposal that will affect the cochlear implant's availability to Medicare beneficiaries. We urge CMS to revisit the proposed payment determinations.

Thank you again for the opportunity to present our views with respect to these proposed revisions to CMS policy.

Sincerely,

J. Louie Yilling
Director of Finance
MedEl Corporation

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33

September 10, 2007

The Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Re: CMS-1392-P
Necessary Provider CAH's

To Whom It May Concern:

This letter serves as a response to the proposed rule published in the August 2, 2007 Federal Register regarding the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates. Our firm, Parrish, Moody & Fikes, p.c., is a public accounting firm located in Waco, Texas that specializes in healthcare. Our firm currently services more than 100 rural hospitals throughout the State of Texas. We have observed those 100 hospitals operating under conditions of panic as a result of continuous Medicare cuts in reimbursement. As a result of the continuous Medicare cuts and declining volume of patients in the rural areas of Texas, we have assisted in the conversion of over 30 of the rural hospitals in Texas to critical access hospital status.

We are specifically commenting on the paragraph that states: *"In the event that a CAH with a necessary provider designation enters into a co-location arrangement after January 1, 2008, or acquires or creates an off-campus facility after January 1, 2008, that does not satisfy the CAH distance requirements in Section 485.610(c), we are proposing to terminate that CAH's provider agreement, in accordance with the provisions of Section 489.53(a)(3)."*

Our interpretation of this proposal is such that it prohibits any additional growth of outpatient services to population areas of the state that are already designated as Health Professional Shortage Areas or Medically Underserved Areas. In most of the critical access hospitals we represent, many of them own or operate rural health clinics or already existing outpatient departments of the hospital such as physical therapy or geropsych that are located within close proximity of the main campus. These facilities do meet all the requirements of the Provider Based Regulations. Logically, it is a very cost-effective way to expand access to primary health care services in many rural and frontier areas.

With the proposal above, it appears CMS would deny a critical access hospital future opportunities to provide additional outpatient services to population areas in a rural or frontier area where the population is declining and there are no other sources of healthcare services. While volume is always an issue in the rural areas and hence the reason for the critical access hospital status in the first place, it appears the elimination of future growth of outpatient services would be another reason for declines in volume in the rural areas. With costs currently plaguing our hospitals and volume decline driving the cost per unit of service up higher than needed already, the denial of future outpatient services will continue to plague the cost per unit. It is evident that growth and volume are important issues. Rural hospitals already experience lower rates of volume from year to year that are typically beyond the hospital's control.

In conclusion, we strongly recommend CMS eliminate the termination of provider for acquiring or creating off-campus facilities after January 1, 2008. With a financial loss such as the closure or termination of a rural hospital, it would be difficult to replace and a significant amount of the Medicare and Medicaid population in those areas would suffer because of it.

If you have any questions, or we can provide more information, please feel free to call.

Sincerely,

PARRISH • MOODY & FIKES, p.c.

William M. Parrish, CPA
President

AMO®
ADVANCED MEDICAL OPTICS

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September 10, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

VIA FEDERAL EXPRESS

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates; Medicare and Medicaid Programs: Proposed Changes to Hospital Conditions of Participation; Proposed Changes Affecting Necessary Provider Designations of Critical Access Hospitals

Dear Acting Administrator Weems:

These comments are submitted by Advanced Medical Optics, Inc. (AMO), a global leader in the development, manufacturing, and marketing of medical devices for the eye. In addition to a variety of intraocular lenses (IOLs) for patients with cataracts and refractive disorders, AMO makes the Baerveldt Glaucoma Shunt. It pleases us that many Medicare beneficiaries first encounter the Medicare system in the course of having an IOL implanted during cataract surgery. At AMO, we strive to make this first encounter safer, more efficient, less painful, and continually better with respect to visual outcomes. Medical device innovation is instrumental in improving the productivity and quality of life of America's senior citizens. As the longevity of Americans continues to increase, managing chronic diseases like glaucoma becomes even more important in preserving high quality vision for these patients.

We appreciate this opportunity to comment on the proposed rule published in the Federal Register on August 2, 2007, which proposes, among other changes, CY 2008 payment rates for procedures performed in an ambulatory surgery center (ASC).[1] We reiterate our support for the revised ASC payment system, and commend CMS for its efforts in developing the new system. However, we have two brief comments, one regarding the CY 2008 payment for the implantation of the Baerveldt Glaucoma Shunt (and other similar shunts) and the other regarding a technical issue for future comment submission. Our specific comments follow.

[1] See Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2008 Payment Rates, 72 Fed. Reg. 42628 (August 2, 2007) (the Proposed Rule).

I. Proposed CY 2008 ASC Payment for CPT 66180

A. The 2008 payment shortfall for CPT 66180

CPT 66180 describes the implantation of an aqueous shunt for the treatment of glaucoma. The Baerveldt glaucoma implant is one type of shunt that is implanted as a part of the procedure described by 66180. This procedure is usually the final treatment option for patients with glaucoma that is either end stage or nearing end stage. Patients undergoing a glaucoma shunt procedure have typically used multiple eye drops and had both laser surgery and a trabeculectomy prior to being offered a glaucoma shunt procedure. Without this procedure to lower the intraocular pressure, patients would almost certainly go blind from their glaucoma.

Through 2007, the implants (or shunts) used for the glaucoma shunt implantation procedure (66180) are paid separately in the ASC as a prosthetic according to the DMEPOS fee schedule. Beginning in 2008, prosthetic devices (including the Baerveldt glaucoma shunt) will no longer receive separate payment in the ASC, but instead will be packaged with the associated surgical procedure (66180), as this procedure is not considered device-intensive.

Packaging of the device with the associated surgical procedure and indexing the ASC payment to the OPPS payment provides adequate payment for 66180 once the new ASC payment system is fully implemented. As you know, there is a four year transition that begins in 2008 with part of the 2008 payment rate based on 75% of the 2007 ASC payment rate and the other part based on 25% of the fully implemented payment rate.

CMS's calculation method for the 2008 transition payment rate creates a payment shortfall for 66180. The 2007 payment rate that comprises 75% of the CY 2008 first year transition payment is based only on the 2007 ASC group 5 payment of $717 (2007 ASC payment for CPT 66180 but not including the device). In the 75% of the first year transition payment based on the 2007 payment, there is no accounting for the glaucoma shunt, resulting in a significant underpayment during CY 2008 for the resources used in the 66180 procedure. The payment for the glaucoma implant for 2007 is approximately $650, and this amount is unaccounted for in the part of the 2008 transition payment that is based on the 2007 payment rate.

B. Potential solutions to this payment shortfall problem

We offer two ways in which CMS can compensate for this payment shortfall:

1. Pay the fully implemented rate for 66180 in 2008

CMS has already calculated the fully implemented ASC payment for 2008. For 66180, this payment is $1691.11 versus the transition payment of $960.53 (which does not adequately account for the glaucoma implant). The difference between these two payment rates adequately accounts for the device. Applying the fully implemented payment to 66180 for 2008 would be the administratively easiest solution to the problem because CMS has already calculated these values.

2. Include the 2007 device payment in the transition year payment calculation

Another approach to account for the device in the 2008 payment for 66180 would be to include the current payment for the device in the 2007 payment rate that is used to calculate 75% of the transition payment. Using $650 as an approximate 2007 payment for the glaucoma implant (from the DMEPOS fee schedule), the transition payment would be approximately $1,448 = (.75)($717 + $650) + (.25)($1,691.11). Although this payment is lower than the fully implemented payment amount suggested in #1 above, it accounts for the device and would allow ophthalmologists to continue to perform the glaucoma shunt procedure in the ASC during 2008 without suffering a significant financial loss on each case.

C. The unique clinical predicament of ophthalmologists providing the CPT 66180 procedure

To compensate for a possible payment shortfall for 66180 in the ASC in 2008, ophthalmologists could (in theory) perform theses cases in the HOPD during the transition. However, CMS has expressly stated that physicians should not select the site of service based on payment differentials. Furthermore, ophthalmologists do not necessarily have the flexibility to move patients from the ASC to the HOPD. As much of ophthalmic surgery has transitioned from the HOPD to the more efficient and cost effective ASC, many ophthalmologists (and in particular anterior segment surgeons who perform glaucoma surgery) no longer maintain local hospital OR privileges. Therefore, in order to adjust to the payment shortfall for 2008, these ophthalmologists would have to either attempt to obtain hospital OR privileges (which can be a lengthy process) so that they could do these cases at the hospital during the payment shortfall period, accept a significant financial loss on each of these cases, or transfer their patients that need the 66180 procedure to another surgeon. Each of these options is unacceptable and unnecessary.

II. Comment Period for NTIOL Requests

We agree with CMS's new NTIOL notice and comment process that is now aligned with (or part of) the proposed and final OPPS/ASC annual rules. CMS is proposing to continue the 30-day comment period on requests for new NTIOL classes that will be published in the OPPS/ASC proposed rule each year. All other items in the proposed rule will have a 60 day comment period. We suggest that for the purposes of administrative simplicity (for both CMS and the commenting public) and even greater harmonization that CMS also make the NTIOL comment period 60 days.

We understand that the original statutory provision mentions "a 30-day comment period on the lenses that are the subjects of the requests."[2] However, we believe that Congress intended that CMS provide *at least* a 30-day comment period. Adjusting the comment period for NTIOL to 60 days so that it is consistent with the rest of the OPPS/ASC proposed rule would be consistent with the statutory provision.

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[2] Section 141(b)(3) of Pub.L. 103-432.

III. **Conclusion**

We appreciate CMS's significant achievement in developing the new ASC payment system. We believe that CMS has the tools to address the issues discussed above so that glaucoma treatment for Medicare beneficiaries is uninterrupted during 2008. Thank you for your attention to these matters.

Sincerely,

Jane Rady (JSM)

Jane Rady
Corporate Vice President Strategy and Technology
Advanced Medical Optics, Inc.

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(35)

September 10, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1392-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: [CMS-1392-P] Medicare and Medicaid Program; CY 2008 Proposed Changes: Proposed Rule

Dear Sir or Madam:

Cochlear Americas is pleased to submit the following comments regarding the above-referenced proposed rule (Proposed Rule).[1]

Cochlear Americas is committed to delivering revolutionary cochlear implant and osseointegrated auditory technologies to help Medicare beneficiaries enjoy, connect to, and interact with a world of sound. We are providing comments on issues that pertain to the OPPS: Expiring Device Pass-Through Payments section.

Our comments here pertain to osseointegrated auditory technologies, also known as the Baha System. Baha was first approved for use in the United States by the FDA in 1996. With its approval by Medicare in November 2005 as an implantable medical device, the door has opened for Medicare beneficiaries with appropriate indications to benefit from it. Many surgeons utilizing Baha are relatively new to the technology and are just becoming familiar with the reimbursement environment for it.

OPPS: Expiring Device Pass-Through Payments

The 2008 proposed regulations indicate that pass-through payment for L8690 (auditory osseointegrated device, includes all internal and external components) will expire December 31, 2008. We respectfully disagree with the proposed discontinuance of pass-through payment for device category L8690 on December 31, 2008. We feel it is premature for CMS to propose payment policy for the 2009 year in the proposed 2008 rule.

The Pass-Through statute provides for a period of between 2 to 3 years to collect adequate data to determine an appropriate device reimbursement rate. In the case of Baha, pass-through payment was effective 1/1/07 and only one year of claims data (covering 2007) will be available when the final rule for the 2009 OPPS payment is published. We believe this to be inadequate for the following reasons:

[1] 72 Federal Register 42628 (Aug. 2, 2007).

1. We are of the view that due to the low volumes of devices being charged using the new code L8690, that a period of 2 years will not be conducive to determining an appropriate device charge history.
2. Many new Baha providers and clinicians are still learning about reimbursement for the surgery and the related processor, which is fit on the patient approximately three months post surgery.
3. Given the history of hospital billing problems for devices, we are concerned that it is premature to set permanent payment policy on speculative data.
4. There is a large variation in device costs associated with CPTs 69714 – 69718 in 2006, further demonstrating the confusion and indicating likely problems associated with low volumes during a limited collection period.

1. Number of devices billed

In our application for a new category pass-through payment status, we projected Medicare utilization in 2006 would be 525 devices. According to the publicly available CY2006 OPPS data released with the Proposed Rule, the utilization was substantially lower than estimated and is closer to 230 devices (based on CPT volume). We do believe that this number will not substantially increase in the years 2007 and 2008. This reduction in anticipated utilization does not support the implied assumption in the proposed CY2008 rule that there will be enough claims data to support expiration of pass-through payment on December 31, 2008.

2. Accuracy of billing

The HCPCS code describing an osseointegrated device, L8960, was effective 1/1/07. Prior to that time, providers used either L8699 (Prosthetic implant, not otherwise specified) to describe the product, or failed to code the implant on the bill. Medicare data specific to L8690 will not be available until the middle of next year (July, 2008) and will be limited to 2007 dates of service. Therefore, we do not believe enough data will be available to accurately determine the hospital's costs associated with the device and the related surgical services in this restricted period of time.

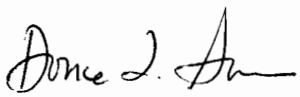
3. Wide variation in device costs

Device costs associated with CPTs 69714 – 69718 range from $5,200 - $9,200 depending on the patient-specific need (please refer to documentation submitted in 2006 in support of the Pass-Through Device Category Application for verification of pricing). With a $4,000 potential difference in device costs, we believe it is inappropriate to assume that sufficient data will be available to support assignment of the procedure to a clinical and resource homogenous APC.

In conclusion, Cochlear Americas appreciates the opportunity to comment on this important CMS proposal that will affect Medicare beneficiaries' ability to enjoy, connect to, and interact with a world of sound. However we believe the proposed decision to sunset the pass-through payment for L8690 after two years effective December 31, 2008 is premature given the lack of available data. We are concerned how this may impact a Medicare beneficiary's access to this technology. We urge CMS to reconsider the proposed decision and utilize the full provisions of the Pass-Through statue by allowing a third year ending December 2009 to capture more accurate and representative data.

Thank you again for the opportunity to present our views with respect to these proposed revisions to CMS policy.

Sincerely,



Donna L. Sorkin
Vice President, Consumer Affairs
Cochlear Americas

Coalition For The Advancement Of Brachytherapy

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September 10, 2007

Via Overnight Delivery

Mr. Herb B. Kuhn
Deputy Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1392-P – CY 2008 Proposed Changes; Proposed Rule
XVI – Proposed Update of the Revised ASC Payment System
H. – Proposed Changes to Definitions of "Radiology and Certain Other Imaging Services" and "Outpatient Prescription Drugs"

Dear Mr. Kuhn:

The Coalition for the Advancement of Brachytherapy (CAB) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to the August 2, 2007 Proposed Rule includes proposed updates to the revised ambulatory surgical center (ASC) payment system. The purpose of this letter is to request that, in light of the recent revisions to the ASC payment system which will permit ASCs to separately bill and obtain payment for brachytherapy sources, CMS consider also revising the definition of "radiation therapy services and supplies" similar to the revisions it is proposing to the definition of "radiology and certain other imaging services."

CAB's Recommendation:

CMS should revise the definition of "radiation therapy services and supplies" set forth at 42 C.F.R. § 411.351 as follows:

> ***Radiation therapy services and supplies*** means those particular services and supplies, including (effective January 1, 2007) therapeutic nuclear medicine services and supplies, so identified on the List of CPT/HCPCS Codes. All services and supplies so identified on the List of CPT/HCPCS Codes are radiation therapy services and supplies for purposes of this subpart. Any service or supply not specifically identified as radiation therapy services or supplies on the List of CPT/HCPCS Codes is not a radiation therapy service or supply for purposes of this subpart. The list of codes identifying radiation therapy services and supplies is based on section 1861(s)(4) of the Act and 410.35 of this chapter, but does not include brachytherapy sources that are "covered ancillary services" as defined at §416.164(b), for which separate payment is made to an ASC.

CAB was organized in 2001 and is composed of the leading developers, manufacturers, and suppliers of brachytherapy devices, sources, and supplies. CAB's mission is to work for improved patient care by assisting federal and state agencies in developing reimbursement and regulatory policies to accurately reflect the important clinical benefits of brachytherapy. Such reimbursement policies will support high quality and cost-effective care. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members and it is our mission to work for improved care for patients with cancer (see Attachment 1).

We would like to thank CMS for the opportunity to meet with staff during the past several years, most recently in June of 2007 to discuss brachytherapy source reimbursement. CAB is committed to working with CMS to identify an appropriate, fair and consistent payment methodology for brachytherapy sources while preserving Medicare beneficiary access to high quality brachytherapy in the ASC setting.

Discussion

On August 2, 2007, CMS issued final rule "CMS 1517-F: Revised Payment System Policies for Services Furnished in ASCs" which, effective January 1, 2008, permits ASCs to directly bill and obtain payment for "covered ancillary services" that are ancillary but integral to ASC-covered surgical procedures including: (a) certain radiology services; (b) certain drugs and biologicals and (c) brachytherapy sources. Pursuant to §416.164(b) payment for these "covered ancillary services" will be made separately to the ASC outside of the ASC composite rate payment. As a result, if a physician-owned ASC bills for ancillary radiology services, drugs, and brachytherapy sources, these billings would likely violate the Stark Law prohibition on physician self-referral because they are "designated health services" or "DHS" that will not qualify for protection under the "ASC composite rate" exception described at 42 C.F.R. §411.351-*Designated health services*.

It appears that, in an effort to address the fact that billings by physician-owned ASCs for "covered ancillary services" may implicate the Stark law, CMS is proposing to modify the definitions of "radiology and certain other imaging services" and "outpatient prescription drugs." CMS excludes from these definitions certain radiology services and drugs that are integrally related to performance of a covered ASC procedure and separately reimbursed as "covered ancillary services." CMS did not, however, propose to revise the definition "radiation therapy services and supplies" to similarly exempt from that definition brachytherapy sources that are provided to a patient that also as an ancillary though integral part of an ASC-covered brachytherapy procedure.

We note that during the Stark II, Phase II rulemaking process, CMS determined that brachytherapy sources could not qualify for protection under the Stark exception for "implants in an ASC" set forth at 42 C.F.R. 411.355(f). CMS specifically commented on this issue in its preamble discussion by stating that "[t]he exception in 411.355(f) applies only to 'implanted prosthetics, implanted prosthetic devices, and implanted DME.' Accordingly, the implantation of radioactive brachytherapy seeds cannot qualify for this exception." See 69 Fed Reg 16111 (Mar. 26, 2004).

As a result, although CMS revised the ASC payment system to permit ASCs to bill and obtain separate payment for brachytherapy sources, relatively few ASCs will be able to submit such claims without subsequently violating the Stark prohibition on physician self-referrals since there is no existing or proposed exception that would protect billing for brachytherapy sources. Therefore we request that, for the same reasons as CMS is revising the definitions for "radiology services" and "outpatient drugs," CMS similarly revise the definition of "radiation therapy services and supplies" to exclude brachytherapy sources that are "covered ancillary services" for which separate payment may be made to an ASC.

We hope that CMS will take our recommendation under consideration during the development of the Final Rule for the 2008 Update to the Revised ASC Payment System. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH, at (703) 534-7979 or Heather Zimmerman, Esq., at (703) 641-4352.

Thank you for your consideration.

Sincerely,

Janet Zeman
Chair

George Clark
Vice-Chair

CC: Carol Bazell, M.D., M.P.H., CMS

Attachment 1

Coalition for the Advancement of Brachytherapy (CAB)

The Coalition for the Advancement of Brachytherapy (CAB) is a national non-profit association composed of manufacturers and developers of sources, needles and other brachytherapy devices and ancillary products used in the fields of medicine and life sciences. CAB members have dedicated significant resources to the research, development and clinical use of brachytherapy, including the treatment of prostate cancer and other types of cancers as well as vascular disease. Over 90% of brachytherapy procedures performed in the United States are done with products developed by CAB members.

Member Companies

BrachySciences
C.R. Bard, Inc.
Cytyc Corporation
IsoRay
MDS Nordion
Mentor Corporation
Nucletron Corporation
Oncura
SIRTeX Medical, Inc.
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August 27, 2007

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Mr. Herb Kuhn
Deputy Administrator (Acting)
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

ATTN: FILE CODE CMS-1392-P

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; **PET/CT Scans; OPPS: Packaged Services**

Dear Mr. Kuhn:

The Academy of Molecular Imaging (AMI) is pleased to have the opportunity to comment on the CY 2008 Hospital Outpatient Prospective Payment System proposed rule, CMS-1392-P (the proposed rule). AMI is comprised of academicians, researchers and nuclear medicine providers utilizing molecular imaging technologies, including positron emission tomography (PET) and PET with computed tomography (PET/CT). AMI serves as the focal point for molecular imaging education, training, research and clinical practice through its annual scientific meeting, its educational programs, and its Journal, *Molecular Imaging & Biology*. AMI speaks for thousands of physicians, providers, and patients with regard to this lifesaving technology, and has worked closely with CMS over the past three years to increase beneficiary access to both standard PET and PET/CT through the development of the National Oncologic PET Registry (NOPR).

Summary

AMI believes that CMS's proposal to reassign PET/CT from a new technology Ambulatory Payment Classification (APC) to APC 308 is inappropriate and unsupported by reliable cost data. By assigning both PET and PET/CT to the same APC, CMS fails to recognize that PET/CT is a clinically distinct technology from conventional PET, with unique clinical benefits. Unlike traditional PET scans, PET/CT is a developing, state-of-the-art technology that will continue to be refined in coming years. The proposed reassignment of PET/CT would risk limiting beneficiary access to a service that now represents the standard of care for most oncology patients.

AMI also urges CMS to continue to pay separately for all diagnostic and therapeutic radiopharmaceuticals that are above the threshold for separate payment. CMS's proposal to bundle all diagnostic radiopharmaceuticals into procedural APCs will

not result in appropriate payment for certain clinically appropriate radiopharmaceuticals and nuclear medicine procedures.

Background on Medicare Payment for PET/CT

PET/CT procedures are identified by three CPT codes (78814, 78815, and 78816). In 2005 and 2006, these codes were assigned to New Technology APC 1514 and the payment rate was $1,250.

For CY 2007, CMS proposed to assign PET/CT to the same clinical APC as traditional PET. However, based on public comments and a concern regarding the accuracy of cost data, the CY 2007 final rule assigned PET/CT to a separate, new technology APC (1511) that paid $950, approximately $100 greater than a single PET scan.

In the current proposed rule, CMS again proposes placing PET/CT in the same clinical APC as traditional PET (0308). In the discussion, CMS states that PET and PET/CT "have obvious clinical similarity." AMI disputes this characterization.

Assign PET/CT to a Separate Clinical APC

PET and PET/CT are clinically distinct technologies that should be classified separately under the APC system. Separate assignment for these technologies is supported by both Medicare regulations and the differences in the technologies.

As CMS notes, all of the items and services within a given APC group must be "comparable clinically and with respect to resource use." With regard to CMS's determination of a clinically appropriate APC, the agency has stated:

> After we gain information about actual hospital costs incurred to furnish a new technology service, we will move it to a clinically-related APC group with comparable resource costs. If we cannot move the new technology service to an existing APC because it is dissimilar clinically and with respect to resource costs from all other APCs, *we will create a separate APC for such service*. (65 FR 18476, 18478 (April 7, 2000))

The combination of PET and CT into a single device, known as a PET/CT, represents a clinical breakthrough in imaging. The integration of the two scans provides the most complete non-invasive information available about cancer location and metabolism. PET/CT identifies and localizes tumors more accurately than either of the component images taken alone. In addition, PET/CT technologists can perform both scans without having to move the patient. The resulting images thus leave less room for error in interpretation.

The benefits of PET/CT to the patient are tremendous: earlier diagnosis, more accurate staging, more precise treatment planning, and better monitoring of therapy. A PET/CT image can distinguish between malignant and benign processes, and reveal tumors that may otherwise be obscured by the inflammation and fibrosis that result from therapies such as surgery, radiation,

and drug administration. PET/CT images often reduce the number of invasive procedures required during follow-up care, including biopsies, and may reduce the number of anatomical scans needed to assess therapeutic response. In some cases, the images are so precise that they can locate an otherwise undetectable tumor. For all of these reasons, PET/CT now represents the standard of care for most oncology patients.

FDA has consistently concluded in both premarket approvals and its regulations that PET/CT is a distinct medical device from PET. New PET/CT devices are specifically cleared by FDA for marketing under the 510(k) process on the basis of currently marketed (or predicate) PET/CT devices, not PET devices.

Moreover, PET/CT technology represents the state of the art imaging for oncology patients. Although CMS has found that 2006 claims data indicates similar resource costs for PET and PET/CT, it is likely that over the next few years the costs of PET/CT relative to PET will continue to diverge. No manufacturers are currently developing new PET scanners. As new PET/CT technologies are developed with different costs from PET, the resource dissimilarity will require a separate clinical APC for PET/CT.

Continue Separate Payment for Diagnostic Radiopharmaceuticals

In the proposed rule, CMS proposes packaging diagnostic radiopharmaceuticals into the payment for diagnostic nuclear medicine procedures, including PET and PET/CT, for CY 2008. AMI believes that it is inappropriate to treat diagnostic radiopharmaceuticals differently from other drugs and that claims data may not accurately reflect radiopharmaceutical costs, resulting in inappropriately low payments for PET and PET/CT.

CMS has traditionally paid separately for diagnostic radiopharmaceuticals that meet the cost threshold for packaging of drugs and biologicals under the OPPS. In the proposed rule, CMS proposes to package payment for all diagnostic radiopharmaceuticals, regardless of the per day cost. In the context of this proposal, CMS has argued that they see "diagnostic radiopharmaceuticals . . . functioning effectively as supplies that enable the provision of an independent service."

AMI believes that this is an inappropriate way to characterize radiopharmaceuticals used in PET/CT scans. Radiopharmaceuticals are unique drugs, and not supplies. Radiopharmaceutical such as FDG clearly qualify under the Medicare statute as specified covered outpatient drugs, and should be paid separately, consistent with the treatment of other drugs and biologicals. This methodology for drug payments is important to ensure that physicians are given the flexibility to use the most appropriate drugs for the clinical circumstances.

Although fluorodeoxyglucose (FDG) is commonly used in PET/CT scans, there are numerous radiopharmaceuticals in development that will be used with PET/CT in the near future. Packaging of radiopharmaceuticals into the PET/CT and PET APCs will undermine the resource homogeneity of the procedure APCs which can involve the use of several different radiopharmaceuticals with widely varying costs. As new drugs for PET/CT come to market, providers will experience substantial resource variation for PET/CT scans based on the different

costs for various radiopharmaceuticals. If CMS packages the costs of radiopharmaceuticals into the procedure APCs, this will be a substantial disincentive for the development of new and better drugs, which will limit research and development of better products.

The packaging approach threatens to undermine CMS's efforts to establish accurate payment for both nuclear medicine procedures as well as radiopharmaceuticals. AMI disagrees with CMS's assertion that the line item estimated costs in CMS "claims data offer an acceptable proxy for average hospital acquisition cost and associated handling and preparation costs for radiopharmaceuticals." Accurate cost data for diagnostic radiopharmaceuticals are needed to set appropriate payment rates, and AMI is concerned that implementation of diagnostic radiopharmaceutical revenue codes have not yet enabled accurate isolation of radiopharmaceutical data and average acquisition costs. CMS claims data may fail to accurately reflect higher cost radiopharmaceuticals. Other methodologies for determining average acquisition cost are more appropriate and accurate.

Finally, the packaging proposal may also raise operational difficulties for providers. CPT and HCPCS Level II coding nomenclature is silent to the indication for each nuclear medicine procedure. Combining these separate codes into one package would create an unnecessarily complex coding system for nuclear medicine procedures. Moreover, combining the costs of these separate codes may create wide variations in costs based on individual patient requirements and physician practices.

AMI requests that CMS continue to pay separately for all radiopharmaceuticals that meet the cost thresholds for drugs and biologicals. We also specifically encourage CMS to work with the Society for Nuclear Medicine, which has done extensive research regarding radiopharmaceutical acquisition costs.

Conclusion

AMI appreciates CMS's continuing efforts to ensure accurate payment for molecular imaging technologies that do not discourage physicians from using the most appropriate tools for their patients. In the final rule, AMI respectfully requests that CMS assign PET/CT to a separate clinical APCs, and continue to pay separately for radiopharmaceuticals that meet the standard cost threshold.

Please do not hesitate to contact me if you would like to discuss these issues further.

Sincerely,

Johannes Czernin, M.D.
President
Academy of Molecular Imaging

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September 6, 2007

Mr. Herb Kuhn
Acting Administrator
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Department of Health and Human Services
Attention: CMS 1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Mr. Kuhn:

Re: CMS 1392-P, Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Rates

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to comment on the proposed changes to the ambulatory surgical center (ASC) payment system for 2008. ASGE represents more than 10,000 physicians who specialize in the use of endoscopy to diagnose and treat gastrointestinal diseases and disorders, such as colorectal cancer.

We are very concerned that CMS has chosen to use the percentage increase in the Consumer Price Index for Urban Consumers (CPI-U) as the update mechanism for ASC services. We think the market basket used for the hospital outpatient prospective payment system (HOPPS) is a much more appropriate index. While the CPI-U was the historic method used to update ASC rates in past years, this was prior to the legislative mandate to revise the ASC payment system and prior to the implementation of HOPPS. As indicated in the proposed rule, the statute does provide flexibility for CMS to utilize a different updating mechanism. A fundamental principle underlying the proposed changes to the ASC payment rates and polices is to increase the consistency between the hospital outpatient department and the ASC payment systems in the future. Thus, with only some limited exceptions, the payment weights for ASC services are based on the weights calculated under HOPPS. Similarly, there is an alignment of packaging and bundling policies under both payment systems. However, for the update mechanism CMS proposes to use a different method for updating payments in the future, with absolutely no policy rationale provided.

ASGE believes that the hospital market basket index, which measures changes in the cost of hospital labor, supplies, equipment, and overhead, is a better index for measuring ASC cost inflation than an index measuring changes in the cost of goods and services purchased by urban consumers. ASC's must compete in the same labor market for nursing, technician, coding, and billing personnel and must pay competitive salaries. Moreover, the identical medical supplies and equipment purchased by ASCs are also purchased by hospitals. Finally, ASCs and hospitals both need to maintain liability insurance. Thus, the changes in the cost of the market basket of goods and services from one year to the next experienced by hospitals inevitably would apply to ASCs as well. In contrast, there is neither evidence nor any reason to believe that an index which measures the changes in the costs of housing, food, clothing and shelter experienced by consumers applies to ASCs. We would, therefore, ask CMS to reconsider their decision and utilize the hospital market basket for the determination of the update factor.

Thank you for the opportunity to offer these comments.

Sincerely,

Grace H. Elta M.D.

Grace H. Elta, MD, FASGE
President

REX
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(39)

September 7, 2007

Herb B. Kuhn, Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS proposed changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates (CMS-1392-P)

Dear Director Kuhn:

Our hospital wishes to thank CMS for the opportunity to provide appropriate comments in response to the proposed 2008 Hospital Outpatient Prospective Payment System and 2008 Payment rates released by CMS on July 16, 2007.

We wish to address the CMS APC assignment for a new technology made effective in program transmittal 1259 dated June 1, 2007. A new technology assignment was approved by CMS specific to the Implantation of the DVS Dosimeter for treatment of cancer patients.

We appreciate that CMS has correctly determined that this technology is new and requires the development of a new APC assignment; however, CMS has made a significant error in the APC assignment for this new procedure and technology.

The new technology code (**C9728**) approved by CMS should include the cost of the implant procedure as well as the DVS sensors. The code assignment made has excluded the cost of the sensors and only accounts for the cost of the implant procedure. In addition, the existing code for implantation into the prostate (**55876**) also excludes the cost of the DVS sensors.

It is our understanding that the purpose of the new technology APC application is to permit hospitals to utilize new technology appropriately to provide care for beneficiaries, and to provide the hospitals a mechanism for reimbursement of new technology. The APC assignments for C9728 and 55876 do not account for the cost of the DVS technology, and the proposed 2008 HOPPS payment system does not offer a mechanism for reporting the DVS technology cost.

We encourage CMS to develop a code that will permit hospitals to report the cost of the technology associated with these two procedures so that cancer patients may have access to this new technology as CMS intended under the APC new technology process.

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Thank you in advance for your time and consideration for this important clinical and hospital reimbursement issue.

Sincerely,

Bernadette M. Spong
VP/Finance and CFO

cc: Carol M. Bazell, M.D., Director, Division of Outpatient Care

Stokes-Reynolds Memorial Hospital, Inc.

PO Box 10
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Danbury, NC 27016

(4C)

September 5, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
Mailstop: C4-26-057500 Security Boulevard
Baltimore, MD 21244-1850

RE: NECESSARY PROVIDER CAH'S

To Whom It May Concern:

This comment letter is with respect to the notice of proposed rulemaking for the Hospital Outpatient Prospective Payment System (OPPS) that includes proposals specific to Critical Access Hospitals (CAH). This proposed rulemaking was published on July 16, 2007 and will be effective January 1, 2008 if implemented.

Stokes-Reynolds Memorial Hospital converted to Critical Access Hospital status effective July 1, 2004 as a necessary provider. It is the only hospital in Stokes County. The northern part of the county centered in Danbury where the hospital is located, is separated from the southern part of the county by the only self-contained mountain range in any single county in the United States, the Sauratown Mountains. There are two off campus facilities located in King, NC that are provider based as part of the hospital. Our current payor mix is 36% Medicare, 9% Medicare Managed Care, 22% Medicaid, 23% Other Third-Party Payors, and 10% Self Pay. Critical Access Hospital status has been instrumental in allowing our hospital to stabilize and provide continued access to acute care services to the county residents.

We are deeply concerned about the proposed rule which will eliminate the ability of a necessary provider, or any CAH, to establish a provider based location including a department or a remote location or an off campus distinct part psychiatric or rehabilitation unit on or after January 1, 2008 that does not meet the distance criteria for CAH from another hospital or CAH. The penalty for not meeting the requirements can be the loss of CAH certification. This proposal has significant devastating potential for Stokes-Reynolds Memorial Hospital. It will take away the capacity and ability for our health care organization to recruit and retain physicians as well as meet the needs of the Medicare beneficiaries in our rural community.

We believe that our ability to recruit and retain physicians in our rural setting will be greatly hampered by this proposed rule. A strong primary care base of physicians is necessary for the support of other specialties such as orthopedics, ophthalmology, general surgery, gastroenterology, urology, podiatry, etc. We are in the midst of developing physician manpower strategies and in order to be able to survive we are increasingly changing from private practice models to an employment model under the control of the hospital. Physicians in our rural outreach areas are finding it more and more difficult to survive and we are considering employment arrangements which provide a higher base compensation to physicians in order to compete with other communities. Currently we are operating one provider based clinic on the main hospital campus and we are considering employing additional physicians off site. It simply is not practical for some of the practices to be on our main campus in order to meet the needs of a rural community that is widely dispersed over 456 square miles.

We believe that the intent of the rule on location of a Critical Access Hospital applies to its main campus and not remote locations. We are in the midst of strategic planning at our remote locations to possibly

integrate the two locations into one single location on one of the existing sites. This will allow us to provide more cost effective service. It will allow us to eliminate duplication of staffing and also eliminate costly upkeep of an aging facility. In addition we can more appropriately meet the needs of the citizens in the community.

We believe that the current system in place that governs provider based entities is already sufficient enough to safeguard against gaming. It is inappropriate to establish a rule to keep the two percent of the CAHs from abusing the CAH designation and punish and/or cripple the ninety-eight percent of us who are functioning appropriately. We therefore, recommend that you drop this provision and encourage you to stay with the existing provisions.

Sincerely,

Lance C. Labine, F.A.C.H.E.
President

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41-0
(5)

August 29, 2007

Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Implantation of Spinal Neurostimulators

I am writing to express my concern over the proposed changes to CMS' OPPS and ASC reimbursement methodologies. In particular, my concern over the proposed rule which I believe will limit patient access to a beneficial technology.

CMS has proposed the elimination of a separate APC for rechargeable neurostimulators, which will directly impact hospital financial considerations, and the corresponding ASC reimbursement methodology. For the past two years, CMS has allowed reimbursement for this new technology, the rechargeable spinal cord stimulator. The additional reimbursement has been available either through a new technology pass-through in the hospital setting, or via the DMEPOS fee schedule in the ASC. The proposed rule to eliminate the pas-through, and group rechargeable stimulators and non-rechargeable neurostimulators into APC 0222, despite a documented significant cost differential, will change the decision process from a clinical decision to an economic decision process.

As a provider in a community in which a hospital has made a financial decision to eliminate this beneficial therapy, I am very concerned that the alternative site of service ASC will be forced to eliminate the therapy as well. The decision will be a direct result of CMS decision to only allow one APC for both rechargeable and non-rechargeable stimulators. Medicare and private payer patients will no longer have access to this valuable therapy.

We recommend that CMS create separate APC's for the rechargeable and non-rechargeable neurostimulators on the basis of the substantial cost differential. We believe that there is a substantial clinical improvement provided by rechargeable neurostimulators, and the therapy is worthy, clinically effective therapy.

Thank you for your consideration.

Cordially,

Jashvant Patel, M.D.
JP/cm

(42)

MOHPA
MINNESOTA ONCOLOGY HEMATOLOGY, P.A.
An Affiliate of US Oncology

September 4 , 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1392-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates Proposed Rule) – OPPS: Payment for Therapeutic Radiopharmaceuticals

Minnesota Oncology and Hematology Professional Association (MOHPA) is a specialized medical group dedicated solely to the diagnosis and treatment of various cancers as well as many blood disorders. We are responding to the 2008 hospital outpatient proposed rule and the proposed payment for therapeutic radiopharmaceuticals; specifically the radioimmunotherapies Zevalin (ibritumomab tiuxetan) and Bexxar (tositumomab) which are indicated for the treatment of relapsed or refractory low-grade non-Hodgkins lymphoma (NHL).

Many of our NHL patients are currently covered by Medicare. The median age of patients with NHL at diagnosis is 66 years. Zevalin and Bexxar are novel therapies that we have found to be safe and effective treatment options for our older patient population, many of whom have difficulty tolerating chemotherapy. These therapies are also administered in only two steps one week apart; the imaging/dosimetric dose with the therapeutic dose following one week later. Compared to several months of chemotherapy, we find this one week therapy to be a very useful alternative for many of our elderly NHL patients.

The payment rates for Zevalin and Bexxar in the proposed rule are significantly below the acquisition cost of these regimens to the hospital. For example, the imaging (In-111 ibritumomab) dose of the Zevalin therapeutic regimen is considered to be a diagnostic radiopharmaceutical in the proposed rule and is bundled into the nuclear medicine procedure (APC 414) payment of $477.60. This payment is nearly 80% below the $2,260 acquisition cost of the In-111 Zevalin dose alone to the hospital (not taking into consideration the costs associated with administering the scan). The proposed payment for the therapeutic (Y-90 ibritumomab) Zevalin dose is $12,030.02. This is nearly 40% below the hospital acquisition cost of $19,625 for the Y-90 dose of Zevalin.

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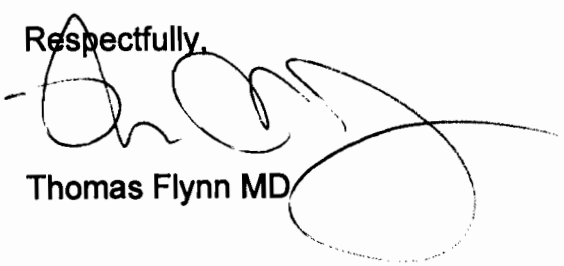
We believe that it will be extremely difficult for hospitals to offer Zevalin and Bexxar to Medicare beneficiaries next year, and we are deeply concerned that access to these important therapies for non-Hodgkins lymphoma will be severely compromised. We recommend that CMS continue to reimburse for the Zevalin and Bexxar therapeutic regimens (both the imaging/dosimetric and therapeutic doses) using the current methodology until a suitable alternative methodology is identified that accurately captures the hospital acquisition and overhead costs.

We appreciate the opportunity to submit these comments, and thank you for your attention to this important issue.

Respectfully,



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September 4, 2007

43

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Rule [File Code: CMS-1392-P]

Dear Administrator Weems:

My name is Chris Laird and I am an Associate Administrator at St. Joseph's Hospital-HealthEast Care System which is a provider of image guided robotic stereotactic radiosurgery and CyberKnife Coalition member. We thank you for the opportunity to comment on the proposed rule for the hospital outpatient prospective payment system for calendar year (CY) 2008, CMS-1392-P "Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates."

Background

Medical linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments to tumors over several weeks while sparing normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT) and image-guided radiation therapy (IGRT), which combined computed tomography (CT) imaging with LINAC technology to identify the location of a lesion before and after a treatment session. In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1950's and 1960's, frame-based stereotactic radiosurgery (SRS) was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual positioning of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image-guided robotic stereotactic radiosurgery (r-SRS) was developed. This technology provides two significant advantages over traditional radiosurgery: (1) no head or body frames are required, and (2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body with a significant decrease in the amount of radiation delivered to normal tissue.

Proposed Treatment of Image-guided Stereotactic Radiosurgery

At present, the OPPS payment system groups SRS in three ambulatory payment classifications (APCs). For CY 2008, however, the Centers for Medicare & Medicaid Services (CMS) has proposed to include two disparate technologies together with r-SRS in these APCs. We strongly disagree with this proposal, because we believe that it does not maintain the degree of coherence in clinical and resource terms that CMS usually maintains and that is exhibited by other APCs. The two technologies are ultrasound ablation of uterine fibroids with magnetic resonance guidance (MRgFUS) and magnetoencephalography (MEG). Neither of these technologies is similar to SRS, and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

MRgFUS is not similar to SRS. MRgFUS is a system by which high intensity focused ultrasound heats and destroys uterine fibroid tissue using sound waves. The mechanism of treatment for MRgFUS is most similar to that of Radiofrequency Ablation (RFA). Both MRgFUS and RFA ablate tissue by raising the temperature high enough to lead to cell death. By contrast, stereotactic radiosurgery utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body (for instance, in the brain, lung, or spine). Because of the longer duration of treatment, the requirements for monitoring and adjusting to patient movement are much greater.

Furthermore, the two technologies differ significantly in resource utilization. Unfortunately, claims information provides little reliable guidance on this point. MRgFUS is performed on very few Medicare patients and, therefore, very few claims are available. In CY 2005, for example, only two claims were submitted with a HCPCS code associated with MRgFUS.

The nature of the two treatments, however, provides a strong indication of resource differences. When performing MRgFUS, the treatment table containing the ultrasound transducer used to perform MRgFUS is rolled into conventional MRI equipment and the table is docked directly onto an existing MR scanner. The same MRI machine used to provide MRgFUS is also used to perform conventional MRI procedures and, therefore, does not represent an additional capital expense for the hospital. Moreover, no separate build-out is needed to house the equipment, since an existing diagnostic suite is used to perform MRgFUS. In comparison, stereotactic radiosurgery requires a lead-shielded vault, complete with special weighted mounting. SRS systems are dedicated to the treatment of tumors and select disorders with high dose radiation; they are not used to perform other procedures that could mitigate resource requirements. Additionally, SRS treatment times are longer. Therefore, both operating and capital expenses are commensurately larger.

We therefore urge reconsideration of the proposal to move MRgFUS into stereotactic radiosurgery APCs. We agree with the agency's assessment in the CY 2007 OPPS final rule that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Magnetoencephalography (MEG)
Similarly, MEG is also substantially dissimilar to SRS. MEG is a diagnostic imaging technique used to measure magnetic fields produced by electrical activity in the brain. MEG, also known as Magnetic Source Imaging (MSI), is much like Magnetic Resonance Imaging (MRI). Both MEG and MRI produce internal images by recording magnetic signals and are used to provide information to aid in diagnosis. Their use is limited to obtaining information about the brain for diagnostic purposes. SRS, on the other hand, is a therapeutic medical procedure that utilizes large, precisely targeted doses of radiation to destroy tumors and treat select disorders anywhere in the body. MEG is also performed on very few Medicare beneficiaries. Between CY 2002 and 2005, no more than 23 claims were submitted for one MEG CPT code. The other two MEG CPT codes together accounted for only eight claims during those years

In light of the significant differences between a diagnostic tool such as MEG and a therapeutic medical procedure such as SRS, we request CMS reconsider its proposal to assign MEG to the stereotactic radiosurgery APCs. Moreover, we agree with the agency's previous comments indicating that resource and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

SRS Treatment Delivery Services
We support CMS's proposal to continue use of HCPCS codes G0173, G0251, G0339, and G0340. We agree with the assessment that these codes are more specific in their descriptors than available CPT codes, and that hospital claims data continue to reflect significantly different use of hospital resources. Adoption of a smaller set of CPT codes with less specific descriptors would not appropriately reflect the resource costs of these procedures to hospitals and would result in violations of the two times rule.

For CY 2004, CMS created two HCPCS codes, G0339 and G0340, in order to accurately distinguish image-guided robotic SRS systems from other forms of linear accelerator-based SRS systems and to account for the cost variation in delivering these services (CMS-1392-P). And, while there is now three years of hospital claims data, examination of the data reveals ongoing confusion among hospital providers about appropriate coding, resulting in cost and utilization data for SRS systems of all types being captured in the image-guided robotic SRS codes.

Since the agency's intent for CY 2008 is to continue using the G-codes for reporting LINAC-based SRS treatment delivery services under the OPPS, and to ensure appropriate payment to hospitals for the different facility resources associated with providing these services, we respectfully suggest minor revisions be made to the coding descriptors for clarification purposes. We

believe that coding confusion and thus inappropriate payments relate to the concept of 'image-guided robotics.' We believe that clarification of the descriptors is necessary in order to achieve the results intended by the agency's 2004 revisions, and we would be grateful for the opportunity to work together to accomplish these goals.

Conclusion

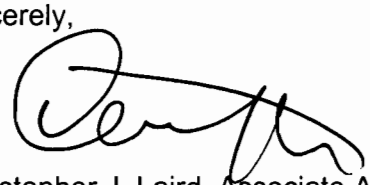
In summary, we urge CMS to:

- Not adopt its proposal to assign MRgFUS to the APCs for SRS. As indicated in the CY 2007 OPPS final rule, retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

- Not adopt its proposal to assign MEG to the APCs for SRS. As recommended by CMS in the August 2005 APC Panel Meeting, resources and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

- Retain the SRS HCPCS codes, G0173, G0251, G0339, and G0340. Further, we request that CMS clarify the associated code descriptors to achieve the agency's goal of distinguishing image-guided robotic stereotactic radiosurgery (r-SRS) systems from other LINAC systems.

Sincerely,



Christopher J. Laird, Associate Administrator
HealthEast-St. Joseph's Hospital
and Member of The CyberKnife Coalition

CJL/let

BRIGHAM AND
WOMEN'S HOSPITAL

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MEDICAL SCHOOL

44

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Ferenc A. Jolesz, M.D.
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Director, Division of MRI
Director, Image Guided Therapy Program
Vice Chairman, Research

September 10, 2007

Herb B. Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850
Re: CMS-1392-P (Hospital Outpatient Prospective Payment System)

Comment Reference: Focused Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

Dear Deputy Administrator Kuhn:

Thank you for the opportunity to submit these comments in response to the proposed CMS HOPPS rule for 2008 in reference to the MRgFUS procedure.

I would like to commend CMS for proposing to move the CPT procedures for MRgFUS (0071T and 0072T) into APC 0067 with a payment of $3,918.43.

Brigham and Women's Hospital has been the worldwide pioneer in MRgFUS research. Together with GE Healthcare and many years before the creation of InSightec, we recognized the potential of MRgFUS as the "ideal" non-invasive surgery modality and conducted some of the ground breaking clinical research.

As a Professor and the Director of the Division of MRI and Image Guided Therapy Program at the Brigham and Women's Hospital Harvard Medical School, I am deeply involved in the development of the MRgFUS technology.

It was raised to my attention that the Cyberknife society submitted a letter, which was discussed and declined by the APC panel, in which they requested that the panel move MRgFUS out of the SRS code quoting dissimilarities between SRS and MRgFUS.
It is my view that both SRS and MRgFUS are image guided surgical systems that are using different kind of energy: SRS-ionized radiation while MRgFUS-acoustic beam but conceptually they share treatment flow and system architecture.

MRgFUS is more advanced since it includes real time monitoring of the treatment outcome, which is making this system an image guided and controlled surgical system compared to image guided only for SRS.

However, it is our opinion that the payment rate for this procedure has, and continues to be, far below the cost incurred by hospitals to provide this service. Average hospital charges for the MRgFUS procedure performed by hospitals range from **$18,000 to $25,000.** The actual costs of this procedure tend to range from **$8,200 to $9,000.**

It has been recommended that the most appropriate APC assignment for MRgFUS, based upon clinical and resource homogeneity, is APC 0127 and not APC 0067 however, this I am sure will be addressed through data collection by relevant hospitals.

To summarize, the proposal to move MRgFUS to APC 0067 has my full support since MRgFUS and SRS have a lot in common. In addition and based on hospital data that will be collected I urge CMS to reassign HCPCS codes 0071T and 0072T to APC 0127 for calendar year 2008 which would more accurately reflect actual hospital charges and costs.

Thank you for the opportunity to provide comments to the proposed rule for hospital outpatient services in 2008.

Respectfully,

Ferenc A. Jolesz, M.D.

Marion R. McMillan MD

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415

September 9, 2007

Re: File Code: CMS-1392-P
Addition of Endoscopic Spinal Surgical Procedures to the Medicare ASC list
CY 2008 OPPS/ASC annual rulemaking cycle

I am writing to request that certain CPT codes associated with endoscopic lumbar and/or cervical spinal disc surgery currently excluded from ASC reimbursement be reconsidered for addition to the list of surgical procedures eligible for reimbursement under the revised ASC payment system through the CY 2008 OPPS/ASC annual rulemaking cycle.

The standard of review used by CMS in determining exclusion of a surgical procedure from payment under the revised ASC payment system has been to exclude any procedure(s) that *"could pose a significant safety risk to Medicare beneficiaries or are expected to require an overnight stay "*. Additionally, CMS has stated that *"it is appropriate to exclude from ASC payment any procedure for which standard medical practice dictates that the beneficiary would typically be expected to require active medical monitoring and care at midnight following the procedure."* I feel that the above criteria are reasonable, and reflect appropriate concerns regarding patient safety following ambulatory surgical procedures. CMS also recognizes that technological advances frequently influence patient risk and postoperative care considerations for surgical procedures, and has invited additional comment concerning reconsideration of procedures that have been previously excluded from payment in ASC's, *"that merit reconsideration as a result in changes in clinical practice or innovations in technology."*

Risk assessment in spinal surgery and the subsequent likelihood that inpatient monitoring and/or observation will be required has traditionally been based on experience with open spinal surgical procedures. Since 1973, sweeping technological advances in endoscopic equipment technology and endosurgical technique have allowed many spinal surgical procedures to be performed in an outpatient setting, with an enhanced patient safety profile and reduced surgical morbidity. Most endoscopic spinal surgical procedures are currently performed in hospital outpatient departments and ambulatory surgery centers under local anesthesia with conscious sedation and no requirement for hospital admission or overnight postsurgical hospital care. As currently practiced, endoscopic spinal surgery generally includes the endoscopic variations of the following established

CPT procedure codes performed alone or in various combinations dictated by individual patient needs and appropriately documented in the operative procedural record:

CPT code	Description
22102	Partial excision of posterior vertebral component, lumbar
22526	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22527	one or more additional levels
62287	Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk, any method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)
62290	Injection procedure for discography, each level; lumbar
63020	Laminotomy, with decompression of nerve root, including partial facetectomy, foraminotomy, or discectomy, single cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; one interspace, lumbar (including open or endoscopically-assisted approach)
63035	each additional interspace, lumbar
63040	Laminotomy, single cervical, reexploration
63042	Laminotomy (hemilaminectomy), withdecompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; reexploration, single interspace, lumbar (including open or endoscopically-assisted approach)
63032	each additional interspace, lumbar
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)

CPT codes 22102 and 62287 are currently recognized and approved for ASC reimbursement. When the proposed additional CPT codes enumerated above are

performed endoscopically under local anesthesia with conscious sedation or brief general anesthesia utilizing current microsurgical techniques, the concern for patient safety and/or the need for overnight monitoring or hospital care applied to open spinal surgical procedures is no longer justified. CMS has appropriately requested that interested parties *"who disagreed with a specific procedure's proposed exclusion from payment submit clinical evidence that demonstrates that the criteria we proposed in proposed new 416.166 of the regulations are not factors when the procedure is performed in the majority of cases. We asked that commenters also provide data to support any assertion that the preponderance of Medicare beneficiaries upon whom the procedure is performed would not be expected to require overnight care or monitoring following the surgery."*

The impressive record of clinical efficacy, patient safety and the appropriateness of usual ambulatory care for endoscopic lumbar and cervical spinal surgery has been borne out over more than 30 years of clinical experience by numerous investigators in the field. A recent multicenter trial of 26,860 operations by 40 spine surgeons at 19 centers reported by Chiu and Savitz (reference 6 below) confirms that greater than 90% of patients were safely and successfully treated as outpatients. Less than 10% of patients required hospitalization or overnight hospital care. These data compare favorably to laparoscopic cholecystectomy, which has been added to the Medicare approved list of procedures eligible for ASC reimbursement effective 1 January 2008. The safety of both procedures has been enhanced and the morbidity greatly reduced through the use of current endoscopic techniques, and outpatient treatment of Medicare and Medicaid beneficiaries receiving endoscopic spinal surgery has become the standard of care. Nonetheless, many physicians and spinal surgeons possibly including those utilized by the CMS medical review staff may be unaware of the significant technical and safety improvements afforded by application of current endoscopic methods to spinal surgical procedures. Accordingly, data from several of these recent studies are referenced below.

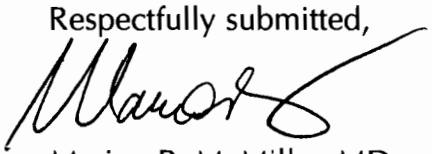
Apart from addition of endoscopic spinal surgery to the approved Medicare ASC listing, practitioners and ASC's have expressed concern for appropriate reimbursement for patient specific consumable supplies and equipment required by the new endoscopic technology. These include single use spinal access kits and laser probes, and disposable shavers, burrs, radiofrequency tissue ablation probes, and other devices required for safe performance of these procedures. CMS has established a precedent for appropriate reimbursement of equipment and supplies for "device intensive procedures", including recognition of similar expenses for spinal cord stimulators and intrathecal pain pumps when performed in an ASC setting or hospital outpatient department, to offset legitimate expenses associated with these devices in addition to the facility costs of providing these services. Accordingly, it seems reasonable to request that CMS provide separate reimbursement for these individual patient specific expenses for consumables and hardware devices required for endoscopic spinal surgical procedures, on an invoice

basis. JOIMAX, Inc., Richard Wolf Endoscopy, and Karl Storz Endoscopy are three of the current manufacturers of disposable equipment and supplies for endoscopic spinal surgical procedures and have been asked to submit current cost estimates for the required patient specific hardware consumables during the public comment period. As CMS has proposed in the 2008 final rule for ASC reimbursement, the facility costs of endoscopic spinal surgery procedures should be reimbursed as a percentage of the reimbursement costs of these procedures when performed in the hospital outpatient department, under the proposed HOPD reimbursement formulae.

As a practicing endoscopic spinal surgeon, I believe that the safety and proven clinical effectiveness of endoscopic lumbar and cervical spinal surgical procedures justifies the addition of these procedures to the approved list of procedures considered appropriate by CMS for reimbursement in ASC's. CMS has affirmed its commitment to expand the breadth and depth of appropriate ambulatory surgical services available to Medicare and Medicaid beneficiaries in the ASC setting. I believe that the addition of endoscopic spinal surgical procedures to the approved ASC list and appropriate reimbursement for the patient specific disposable device related costs of these procedures will help to advance that goal.

I appreciate the opportunity to participate in the annual review of procedures deemed appropriate for reimbursement in the ASC setting and look forward to your favorable reply.

Respectfully submitted,



Marion R. McMillan MD

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Chapter 94

MULTICENTER STUDY OF PERCUTANEOUS ENDOSCOPIC DISCECTOMY

John C. Chiu
Martin H. Savitz

Table 1

Summary of 34,650 cases of endoscopic discectomy from 21 centers

CENTER	CASES	PATIENT SATISFIED	MODIFIED MACNAB	DISCITIS	TRANSIENT CSF LEAK	DYSESTHESIA	MOT/SENS DEFICIT	SECOND SURGERY	DISCOGRAM	MODULATION TISSUE
SAVITZ	300	92%	--	0	0	15	2	5	–	L
CHIU	4000	94%	88%	3	2	9	3	6	+	R, L, B
YEUNG	2600	90%	84%	5(2S)	2	39	2	8	+	R, L, B
BATTERJEE	800	87%	--	1	2	0	1	2	–	R, L
DESTANDAU	4000	87%	--	4(2S)	3	0	0	4	–	B
HOOGLAND	3000	90%	--	0	25	29	25	10	–	L
KAMBIN	300	85%	--	2(1S)	0	5	1	0	–	R
KNIGHT	1700	80%	80%	9(1S)	1	1	1	36	+	L
LEE	8000	94%	82%	16	0	20	8	34	+	R, L, B
LEU	400	89%	82%	7(5S)	0	16	12	15	–	L, B
PEDACHENKO	450	89%	--	11(9S)	0	3	12	21	–	L
PETERSON	300	86%	--	0	0	3	0	0	–	–
RAMIREZ	1200	89%	--	7	7	7	14	8	+	L
REZAIAN	1200	94%	--	1	0	17	3	5	+	L
WOLFF	400	90%	--	0	3	0	0	0	+	L
REUTER	700	90%	86%	6	1	6	6	50	+	R, L
SCHIFFER	2000	90%	84%	2(2S)	0	0	0	45	+	–
MERIWETHER	2000	83%	84%	0	0	90	0	60	–	L
SCHMIDT	400	92%	--	1	4	1	2	0	+	B
WERNER	400	92%	--	2(1S)	0	1	0	0	+	R, L, B
ZHAOMIN + LIU	500	90%	--	3(1S)	0	5	5	3	+	B

S = septic

R = radiofrequency L = laser B = bipolar

Introduction

A multicenter study[9] of percutaneous endoscopic discectomy (lumbar, cervical and thoracic) was published in 2001 with 26,860 operations by 40 spine surgeons at 19 centers of minimally invasive spinal surgery (MISS). The surgical techniques and methods of tissue modulation varied. The incidence of overall surgical morbidity was less than 1%. The reported rate of reoperation was also less than 1%. There was no mortality. Patient satisfaction was over 90% (range 80% - 94%) due to same-day scheduling, keyhole incision, short recuperation, minimal anesthesia, lower analgesics requirement, and early return to work.[16] Because of the efficacy and low morbidity, the conclusions included that endoscopic discectomy had become a significant alternative to open surgery for herniated intervertebral discs.

The world literature for multicenter studies of percutaneous discectomy dates back to 1990 when Onik and a large group of authors[26] reported on automated percutaneous lumbar discectomy (APLD) for small herniations. Successful outcomes were higher (75%) in patients with signs, symptoms, and neuroradiologic imaging of a herniated nucleus pulposus than in patients who had only back pain and degenerative disc disease (50%). Later studies[2-8,12] reported success

rates over 80%. Lee et al.[20] in 1996 concluded that satisfactory outcomes of APLD and chemonucleolysis were similar (80%) compared to laser percutaneous endoscopic lumbar discectomy (PELD) (91%). In a debate between Onik and Kambin,[25] arthroscopic microdiscectomy (AMD) with targeted lateral quadrantectomy was found to be superior to APLD with only medial nucleotomy. Prospective articles by Mayer and Brock[24] in 1993 and Hermantin et al.[12] in 1999 reported that PELD was a satisfactory alternative to laminotomy/microdiscectomy in terms of long-range results, but that patients required less hospitalization, less postoperative pain medication, and less rehabilitation before returning to work. Nevertheless, review articles[1,11,14,19,21] continued to be published concluding that PELD was minimally invasive but only minimally useful for contained small herniations and still experimental. The present study gathered a comprehensive series of percutaneous endoscopic discectomies to assess the overall incidence of complications and morbidity, to determine the rate of reoperation, and to define the current role and efficacy of minimally invasive technique in the armamentarium of a spinal surgeon.

Initially, cervical and thoracic disc herniations and sequestered and migrated fragments or lateral recess syndrome could not be adequately treated.[8,13,17,21] Newer instrumentation, improvements in optics, endoscopically assisted microdiscectomy,[2-9,27,29] and advancements in laser technology (Trimedyne, Irvine, CA) allow removal of large and extruded disc fragments, decompression of bony stenosis, and foraminoplasty.[3,5,10,18,30] Patients with a contained, protruding, or prolapsed nucleus pulposus are now candidates for MISS if evocative discography confirms dynamic herniation.[29]

Procedure

Twenty-one centers of MISS were contacted (Table 1). All 34,650 cases had signs and symptoms of radiculitis and radiculopathy, back and neck pain unrelieved by conservative treatment for at least 6 months, and neuroradiologic findings consistent with disc disease. Ages ranged from 14 to 91, and the sexes were essentially evenly divided. Initially, percutaneous endoscopic technique was effective only for patients with contained lumbar herniations compressing the nerve root.

The various operative approaches (cervical, thoracic, lumbar) have been previously published.[2-6,8,15,18,22-28] In all three areas of the spine, only keyhole incisions were required; and tissue dissection was minimal. Same-day scheduling was the norm, and Band-Aids sufficed for the dressings.

Endoscopy (Karl Storz, Culver City, CA) (Richard Wolf, Vernon Hills, IL) (Smith Nephew, Philadelphia, PA) was easily accomplished except in cases of reexploration for scar tissue. Periannular adipose tissue was removed by coagulation, gauze abrasion, or forceps. Once the nerve root was identified, the annulus was fenestrated with trephines or bluntly opened with an obturator. Manual extraction of disc material employed a variety of microforceps. Disc material which had herniated and migrated into the epidural space or foramen could be

located and extracted. Patients with osteophytes and adhesions compromising the exiting nerve root underwent mechanical and laser foraminal decompression.[15,18] Microrasps were also available for bone removal.

The Nd:YAG laser was employed at 4 centers, and the Ho:YAG laser at 11 centers for hemostasis and disc vaporization; at 4 of the Ho:YAG centers, laser resection of bone and scar was also performed during foraminoplasty. Radiofrequency modulation was available at 7 centers, and bipolar coagulation at 8 centers. At 4 centers where all 3 modalities were available, temperature-controlled, coagulative lesions also shrank fissures by thermal annuloplasty.

Table 1 summarizes the data from 21 centers of MISS. Most cases had same-day scheduling; less than 10% stayed overnight. Of the 80 (0.2%) cases of discitis, only 24 were documented by culture to be septic; all patients recovered with appropriate antibiotic therapy.

The overall postoperative complication rate was 1%, and there was no mortality. Ten surgeons recorded all 50 (0.1%) cerebrospinal fluid leaks; none of the patients required open surgical repair. The most common sequela was 267 (0.8%) cases of dysesthesia, but there were only rare instances of progression to reflex sympathetic dystrophy; if nonsteroidal antiinflammatory drugs were ineffective, alpha blockers and a full series of sympathetic blocks were prescribed. Not all of the 97 (0.3%) motor and sensory deficits were transient but the overall patient satisfaction rate was 90% (range 80%-94%). Modified MacNab criteria were used at 8 centers, and the success rate averaged 84%. There were 312 (0.8%) patients who required early second surgery.

Summary

Fifteen years of experience, advancements in endoscopic monitoring, and refinement of instruments have provided continuous observation of removal of degenerated nucleus pulposus, exploration of the epidural space, location of extruded fragments, and decompression of bony osteophytes and stenosis. Medial nucleotomy is only the start of the PELD technique[3,5,28] after verification of the safety of the nerve root followed by targeted fragmentectomy, examination of the spinal canal, thermal modulation of fissures, laser application, and mechanical foraminoplasty.[15]

The surgical outcomes of 34,650 percutaneous endoscopic discectomy procedures (lumbar, cervical, and thoracic) document a number of advantages over open laminotomy for microsurgical removal of a herniated or extruded intervertebral disc. There has been no reported mortality, no complication of conscious sedation, and no need for blood transfusion. The recorded number of cases requiring early second surgery remains extremely low (0.8%). High patient satisfaction (range 80%-94%) was due in large part to the overall morbidity being 1%. More and more patients are becoming aware of the advantages of minimally invasive spinal surgery: same-day scheduling, laser assistance, small incisions, shorter recovery, reduced surgical and hospital charges, and less time out of employment.

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Surgical Techniques in Orthopaedics and Traumatology 55-120-C-40

Transforaminal endoscopic discectomy with foraminoplasty for lumbar disc herniation

T Hoogland

Abstract. – *In 1994, special foraminal reamers were developed by the author with the purpose of enlarging the spinal foramen through a far posterolateral approach. This made it possible to approach the spinal canal through the lateral foramen and to remove extruding and sequestrated disc fragments from the anterior epidural space. With the aid of a spinal endoscope, it became possible to safely decompress dura and spinal nerves in the lumbar area. Since 1999, all types of lumbar disc herniations have been removed in this fashion. As the method includes bony decompression (foraminoplasty) in case of stenosis, the procedure is also suitable in cases of a combination of spinal stenosis and herniated discs. Since 1999, the procedure has been performed by the author in over 1,500 patients with a recurrence rate in the first year of less than 5%, one case of discitis (less than 0.1%) and no patients with permanent nerve damage.*
The clinical results are at least comparable to the results of the dorsal open, microsurgical or micro-endosurgical techniques.

Keywords: spine, lumbar disc herniation, formaminoplasty, spine endoscopy, discectomy.

Introduction

Because of the fear of complications in lumbar disc surgery, minimally invasive procedures have gained significant interest for both patients and spine surgeons [2, 3, 4, 5, 6, 8, 10, 11, 12]. In traditional dorsal surgery for herniated discs, it is necessary to remove a part of the ligamentum flavum and a part of the lamina; at the L4-5 level, parts of the facet ligaments and the facet joint capsule are sometimes removed in order to visualise the compressed nerve root. In the dorsal approach, usually performed under general anaesthesia, the nerve root has to be mobilised and is therefore at risk of damage.

During the removal of loose disc fragments from the intervertebral space, there is a small risk of perforating the anterior longitudinal ligament or the abdominal aorta with serious and sometimes fatal consequences. The far posterolateral approach to the intervertebral disc and the epidural space presents significant advantages as compared to the dorsal approach, as there is no damage to significant structures that may cause scar tissue or instability [9].

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Therefore, this approach reduces the chances of the so called "post-discectomy syndrome". Kambin has described in detail the closed percutaneous posterolateral approach to the intervertebral disc. However, with the system described by Kambin, it is difficult to reach extruded and sequestrated disc fragments. Moreover, with this system there is a risk of compressing and irritating the exiting nerve root and its ganglion. Because of the limited size of the foramen, in cases of foraminal stenosis the risk of irritating the exiting nerve root is further increased.

With the THESSYS™ (Thomas Hoogland Endoscopic Spine System), however, it is possible to enlarge the intervertebral foramen and to decompress foraminal stenosis. The subsequent guiding rods and cannulas are, first of all, placed in the inferior and more medial part of the foramen away from the exiting nerve root. The foramen is enlarged with special reamers, so that the inferior part of the foramen is also widened in a medial direction, making it possible to advance the working channel into the spinal canal. This means that despite the close proximity of the exiting nerve root, its damage can be avoided by a step-wise enlargement of the lateral intervertebral foramen, as the working instruments and reamers can be guided and directed inferiorly and medially away from the root.

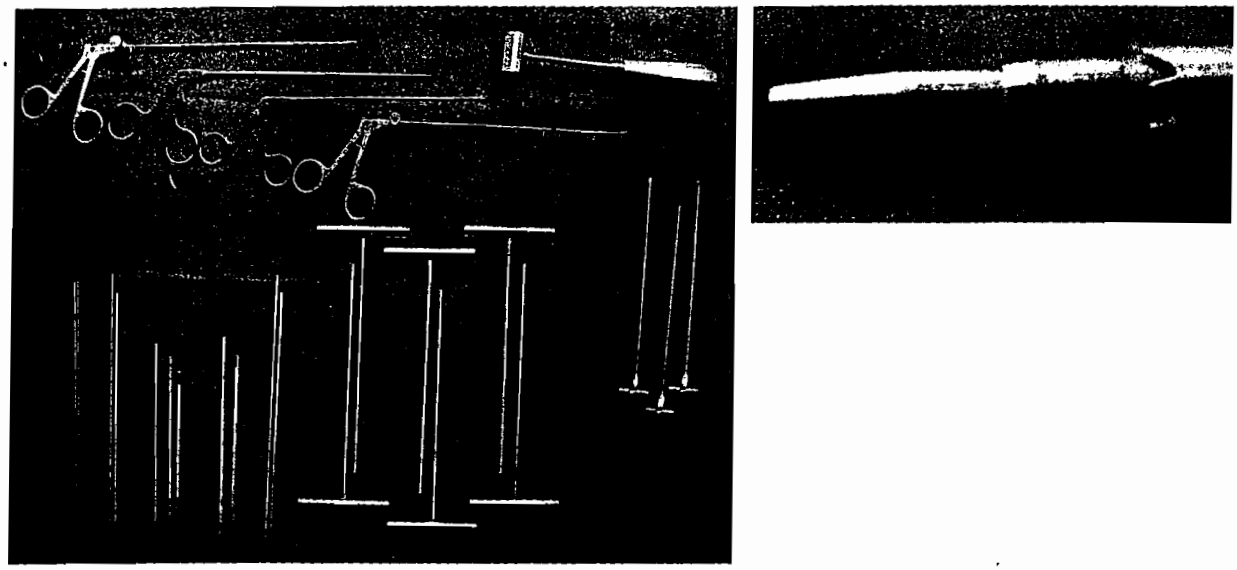
Damage to the transiting nerve root, on the other hand, can be avoided because it is usually displaced medially and dorsally by the prolapsed or extruded disc.

As the reamers are not advanced further than the guiding rod, dura and nerve root lacerations can be avoided.

With THESSYS™ it is also possible to decompress foraminal stenosis. The procedure is performed under local anaesthesia, thereby eliminating the risks of general anaesthesia and thrombosis.

Moreover, the chances of infection are reduced. The procedure is performed under the guidance of the image intensifier and endoscopic visualisation. Dural fistulas and aortic perforations have not been encountered with the use of this technique.

This procedure requires that the surgeon have a perfect three-dimensional view of the spinal structures. The surgical technique involves many steps that must be checked by X-ray intensifier. The surgeon must be able to assess the amount of capsule and bone to be removed from the facet joint in order to achieve a safe portal for the working cannula, while the patient is administered only local anaesthesia. There



1 *THESSYS® (Thomas Hoogland Endoscopic Spine System).*

may be a long learning curve for the spine surgeon before he can reach all types of disc extrusions and sequestrations [7].

Surgical technique

This procedure requires extensive technical equipment including a radiolucent operating table, preferably without metal components in the imaging field, an adequate C-arm image intensifier, a lumbar support pillow, a spinal endoscope with a working channel including camera, monitor and video-recording.

The surgical instruments include an 18-gauge spinal needle, a 22-gauge spinal needle, three K-wires that pass through an 18-guage spinal needle, a set of dilating rods of 2, 3, 4 and 5 mm, a set of dilating cannulas of 3.5, 4.5 and 5.5 mm, a set of special foraminal reamers ranging from 3 to 8 mm, a working cannula of 7.5 mm, a grasping forceps that fits through the endoscope with a working channel, and 3 different sized grasping forceps that fit through the working channel *(fig 1)*.

Pre-operative documentation

Sagittal and axial T2 MRI images are necessary to verify the localisation of the protruded, extruded or sequestrated disc material *(fig 2A, B)*.

A lateral X-ray of the lumbar spine is necessary to verify the precise level of the herniation and to judge the size of the involved foramen. The size of the foramen determines, in conjunction with the size of the patient, how far lateral the entrance point of the procedure will be. In case of a large foramen, as is usually present at the L3-4 and L2-3 level, the approach distance is no more than 10 cm from the midline. The L4-5 and L5-S1 levels are usually approached at least 12 cm from the midline.

2 *A. Sagittal MRI showing protruded disc material. B. Axial MRI showing protruded disc material.*

This distance increases in cases where there is obesity, a very narrow foramen or facet arthrosis.

The patient is positioned on his side on a lumbar support pillow and stabilised with a strap over the trochanter. Anaesthesia is administrated intravenously, with sedatives and morphine-type analgesia on standby. The level of anaesthesia should be not be deep and it should be possible to arouse the patient at any time. The patient's back is disinfected and a sterile screen-type drape is applied.

The image intensifier should be able to swing freely in two directions without interfering with sterility.

PROCEDURE FOR A L5-S1 EXTRUDED DISC HERNIATION

The most important part of transforaminal endoscopic discectomy is to introduce through the lateral foramen, in a safe manner, a working cannula into the spinal canal just short of the location where the extruded or sequestrated disc herniation is located, as demonstrated on a plastic model *(fig 3)*.

The procedure is presented below step by step. The first 13 steps are necessary to introduce the working channel in the correct position, after which the endoscope is introduced and removal of the herniation is performed.

Step 1: The entrance point of the procedure is determined by marking: a) the middle of the spine, b) the iliac crest, c) the estimated lateral distance at the L5-S1 level, usually at 14 cm. A long instrument is placed in the direction of the pathway and a lateral X-ray image is made.

A line is drawn towards the position of the extruding fragment in the lateral projection. The line of approach and the lateral distance are marked *(fig 4)*.

Step 2: The skin is locally infiltrated with 5 cc of 2% lidocaine with adrenaline. Then, an 18-gauge needle is introduced, aiming at the lateral foramen. Usually, at first the facet joint is hit and the position of the needle is verified with the image intensifier in AP and lateral views. The best entrance point to the foramen is just above the facet joint *(fig 5, 6)*.

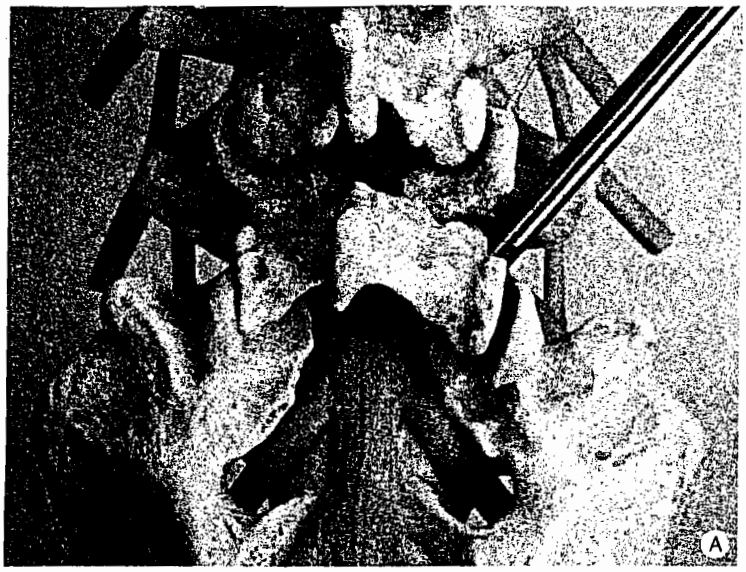
Step 3: A curved 22-gauge needle is then introduced through this 18-gauge cannula and the tip of the second needle is directed caudally and medially, aiming for the extruding disc fragment *(fig 7)*.

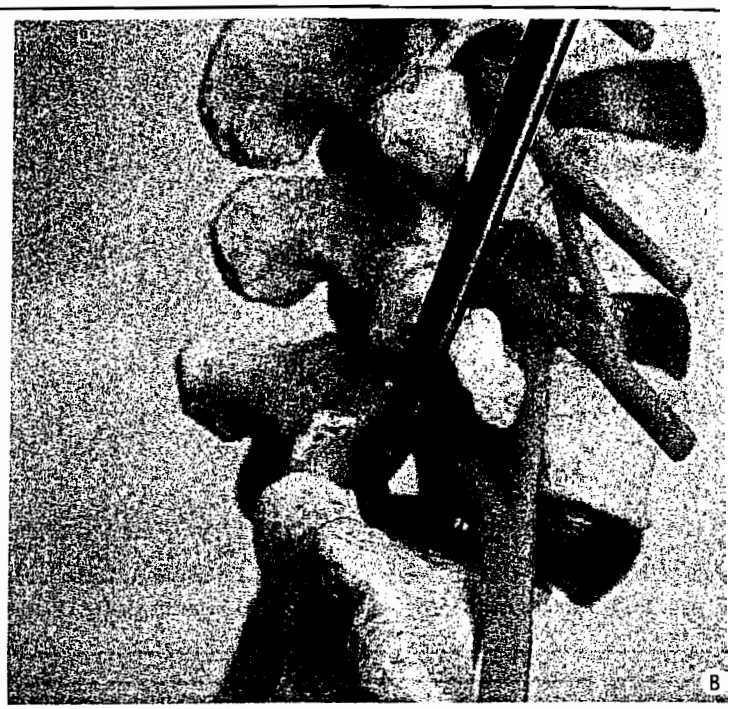
Step 4: The 18-gauge needle is now pushed over the 22-gauge needle. Then the 22-gauge needle is removed.

Step 5: A K-wire is now introduced through the 18-gauge needle and the 18-gauge needle is removed.

Step 6: A 6 mm skin incision is made over the K-wire and a 2 mm dilating rod is pushed over the K-wire.

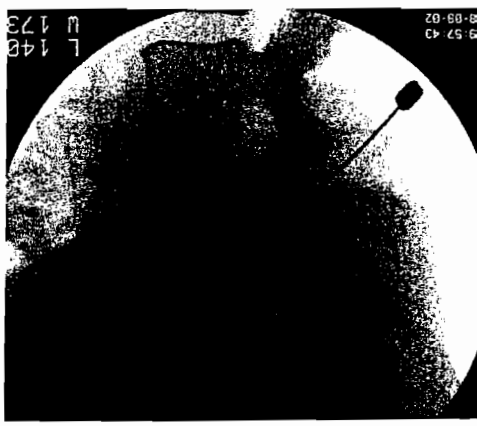
Step 7: The 3 dilating cannulas are now pushed over the first dilating rod in a subsequent fashion.





3 *Cannula positioning in a model.*
A. AP view.
B. Lateral view.

4 *The line of approach and the lateral distance are marked.*



6 *Lateral image verifies the needle position.*

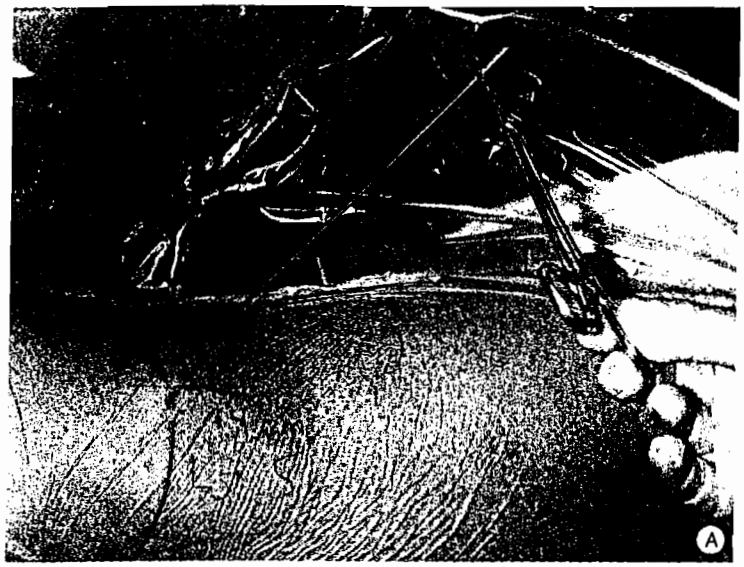
5 *Far lateral introduction of a spinal needle.*

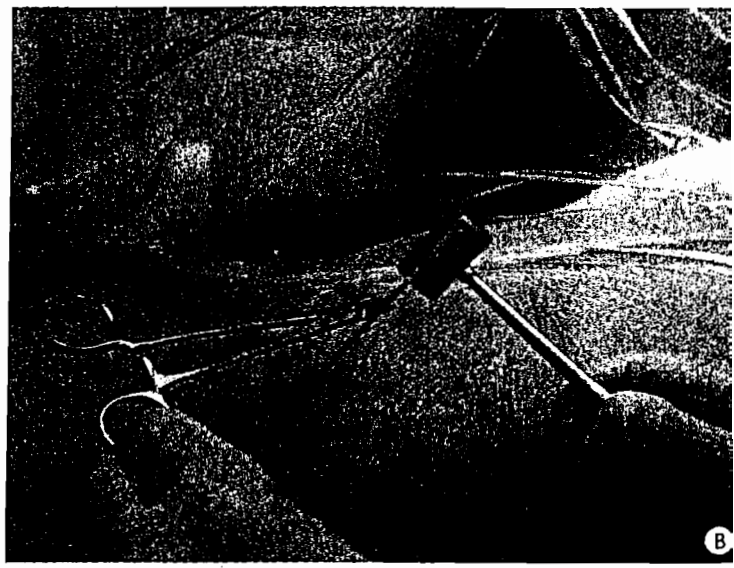
7 *Lateral image demonstrating the placement of the curved needle through the first needle.*

Step 8: The last dilating cannula remains, the other two are removed and 10 cc of local anaesthesia is now infiltrated around the facet joint and around the iliac crest.

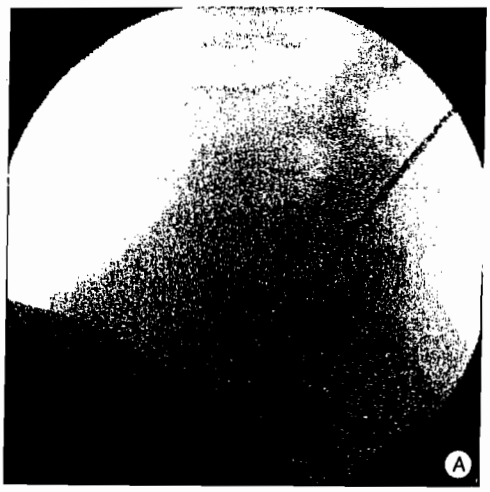
Step 9: The first guiding rod is removed and the curved 2 mm guiding rod *(fig 8A)* is now pushed over the K-wire with the aid of a hammer and imaging control in two directions *(fig 8B)*.

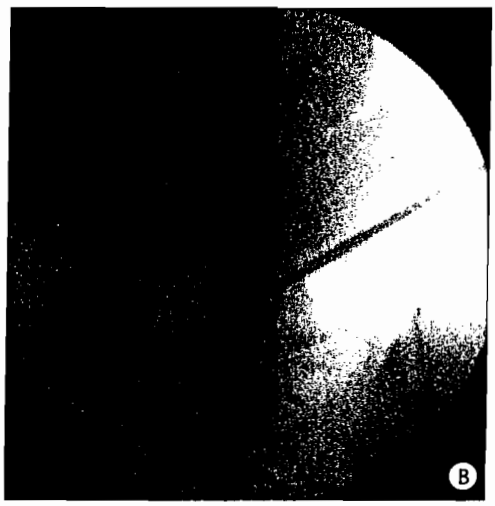
The tip of the curved dilating rod should now reach the centre of the extruded disc fragment *(fig 9)*.





8 *A, B. The first guiding rod is removed and the curved 2 mm guiding rod (A) is now pushed over the K-wire up with the aid of a hammer and X-imaging control in two direction (B).*





9 *The direction of the curved rod is checked. A. Lateral view of the curved rod. B. AP image of the curved rod.*

10 *The first dilating cannula is pushed over the dilating rod.*

With a needle holder, the direction of the curved 2 mm guiding rod is marked in order to check the direction of the curve.

Step 10: The first dilating cannula is pushed over the dilating rod and the first foraminal reamer is pushed over this rod, and then reaming is performed up to the epidural area *(fig 10, 11)*.

Step 11: The K-wire is left behind, all othe instruments are now removed, and a 3 mm dilating rod is now introduced over the K-wire.

At this point the K-wire is removed and the tip of the guiding rod is carefully directed towards the extruded fragment, usually by pushing the rod more interior and more medial, again with the aid of a hammer.

Then the K-wire is once again inserted and a 4 mm dilating cannula is introduced. Over this cannula, the 5 mm reamer is introduced; with this reamer the foramen is enlarged, again up to the epidural space.

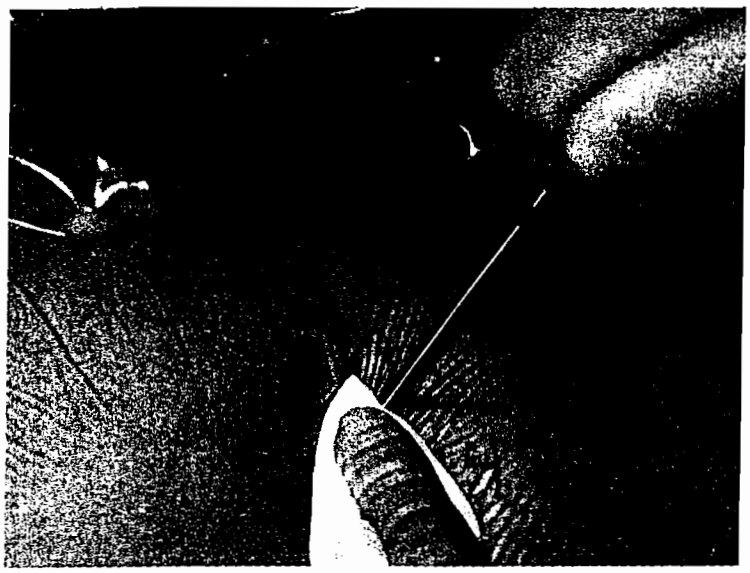
Step 12: Except for the K-wire, all instruments are removed and the 5 mm dilating rod is introduced. The K-wire is removed again and the tip of the rod is placed in the area of the extruded fragment. Then the K-wire is re-introduced, a 6.5 mm dilating cannula is introduced, and over this cannula the 7.5 mm reamer is introduced, again enlarging the foramen *(fig 12)*.

Step 13: After removal of the reamer, the working channel is now put in place.

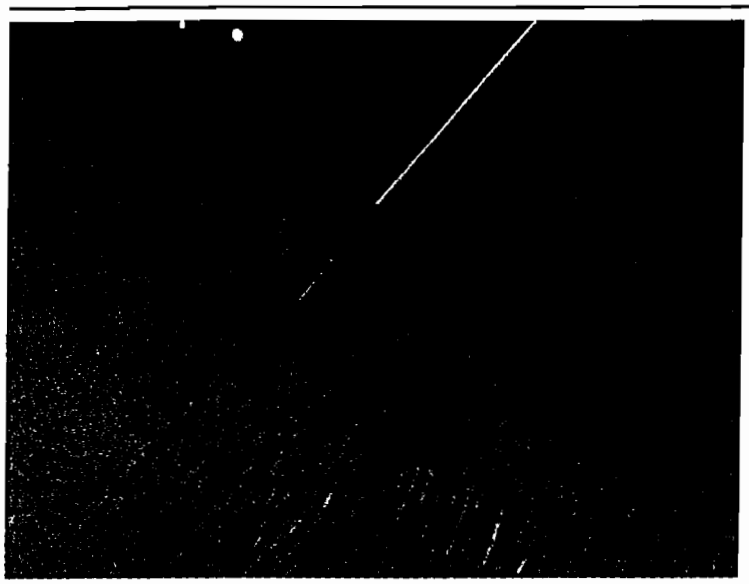
Step 14: The spinal endoscope is now introduced *(fig 13)* and the foraminal area is inspected, usually demonstrating the herniated fragment *(fig 14)*, and, sometimes in the medial area, a part of the compressed nerve root as well. Through the working channel of the endoscope, a forceps is introduced, picking into the depth and removing loose disc fragments to exclude dura or nerve root at the end of the working channel.

Step 15: The endoscope is removed and a grasping forceps is now put on the extruded or sequestrated disc fragment. The position of the grasping forceps is checked with the image-intensifier and at this point X-rays are made in two directions *(fig 15)*.

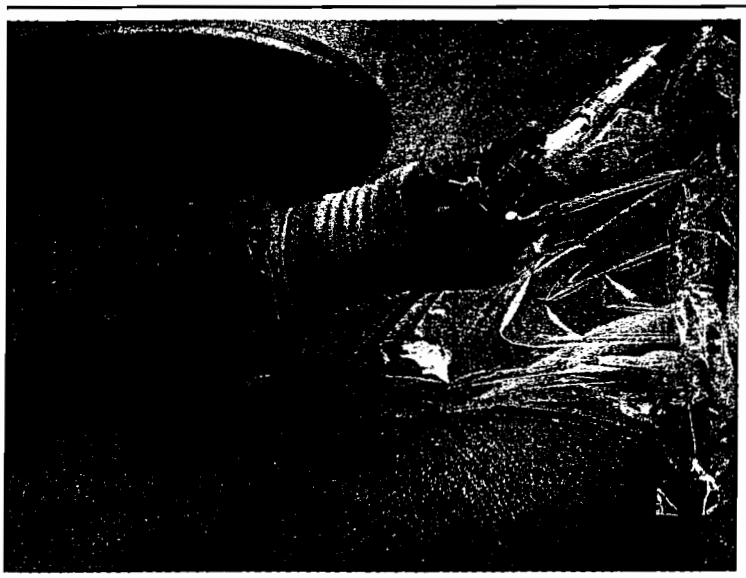
Step 16: The extruding fragment is now removed by means of the forceps.



11 *Reaming is performed up to the epidural area by means of the foraminal reamer.*

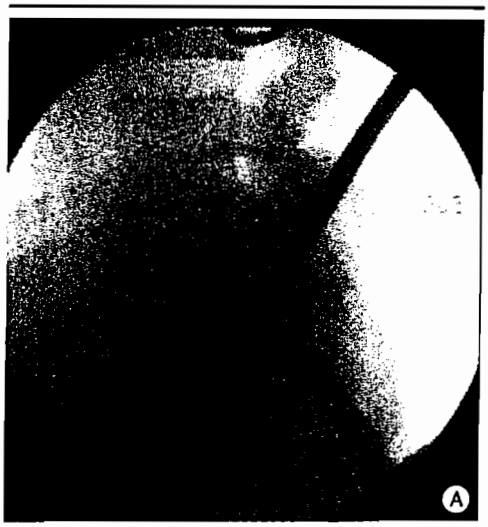


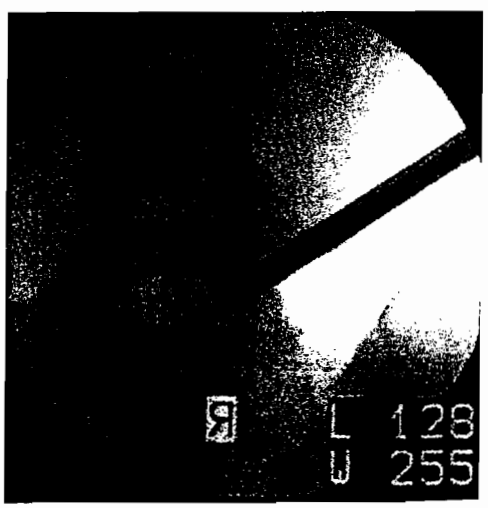
12 *The 7.5 mm reamer is introduced over the cannula.*



13 *Introduction of the spinal endoscope.*

14 *Endoscopic view of herniated fragment and lateral facet capsule. 1. Lateral facet capsule; 2. herniated fragment.*





15 *The position of the grasping forceps is checked with the image intensifier and X-rays are made in two views.*
A. Lateral image view.
B. AP image view.

With repeated manoeuvres all fragments are extracted. At this point the patient should be fully awake so that no neural elements are damaged.

Step 17: The endoscope is re-introduced, looking for the freed nerve.

At the same time, with the working channel forceps, remnants of the extruding fragments are removed. A free and pulsating nerve root must be verified *(fig 16, 17)*.

Step 18: The open end of the working cannula is now turned 180° and with several forceps the posterior part of the disc is now cleared of loose fragments. Finally, with a curved 22-gauge needle, the intradiscal space is irrigated with an antibiotic solution and the cannula is removed. The skin is closed with one stitch.

16 *Endoscopic view showing the removal of the herniation.*

17 *Endoscopic view showing the freed nerve (1).*

Post-surgical care

The patient remains in the recovery room for two hours after the operation and is then mobilised with a semi-firm lumbar brace. The patient can either walk to his hospital room or be sent to a nearby hotel or home.

The patient is allowed to sit for half an hour at a time and can walk short distances. The next morning, a check-up is performed, and after one week a physiotherapy programme is started with mobilising and muscle-strengthening exercises. After three months, a clinical check-up is performed with a control MRI to verify the healing of the herniation, and a strength test of the back musculature.

Results and complications

In a study of 246 patients treated with endoscopic discectomy, at two years an excellent or good result was reported by 86% of the patients, with a unsatisfactory rate of 7.7%. There were no serious complications, and in particular no deep infections. Three patients had disturbing postoperative paraesthesia and partial weakness of the foot and toe extensors, that in all cases resolved over a period of about 3 months. In one patient, a transient allergic reaction occurred due to a prophylactic cephalosporin antibiotic. The re-operation rate was 3.5% in the first year.

If there is strict adherence to the surgical protocol, no other serious complications are to be expected. Care must be taken to have adequate intravenous analgesia with sedation to a level that the patient will feel and report root pain. Each step of the procedure should be controlled in two directions by the image intensifier, particularly when the instruments approach the foramen and the spinal canal. Rarely, lacerations of the anterior dura may occur and, as a rule, remain without consequence. Postoperative headaches are extremely rare; when they occur, they are short-lived.

A recent publication on posterolateral endoscopic excision for lumbar disc herniation by Yeung [13] reported a satisfactory result in 89.3% of the cases and a poor outcome rate of 10.7%. It combined a major and minor complication rate of 3.5%, including 0.6% disc space infections and one case of re-operation for a dural tear.

With a average follow-up of 19 months, there was a re-operation rate of 5%.

Hermantin [1] compared the results of open discectomy with those of endoscopic posterolateral discectomy. There were 97% good results in the endoscopic group (n = 30) and 93% good results in the open laminectomy group (n = 30). However, in this series extruded herniations at the L5-S1 level were excluded.

Indications and limitations

Endoscopic transforaminal decompression can be used for any type of disc herniation that requires surgical intervention. It is obvious that contained disc herniations can be reached more easily than sequestrated herniations, but with THESSYS® the foramen can be sufficiently enlarged to allow introduction of an adequate working cannula into the spinal canal; thus all herniated fragments can be reached, with the exception of disc fragments that have moved on the dorsal (posterior) aspect of the dura, a very rare occurrence.

Limitations of the procedure include the need for specific operating room equipment and special instruments, as well as the long learning curve, particularly for sequestrated fragments. The surgeon needs a good 3-dimensional sight of the lumbar spinal contents and a stereotactic feeling when the instruments are introduced and when the foraminal reaming is performed.

Conclusions

The procedure described above has several advantages: it can be performed under local anaesthesia, thus eliminating the potential complications of general anaesthesia. As the affected nerve root is not anaesthetised, there is a much larger safety margin concerning the risk of neural damage with this procedure, compared to open procedures performed under general anaesthesia. The ligamentum flavum and dorsal joint capsule are not injured; therefore, there is much less scar formation compared to posterior procedures. There is very little postoperative pain and an early return to work is therefore possible. When the specially developed reamers are used, it is possible to remove all types of disc herniations. The incidence of re-operations is not higher than in dorsal approaches and the over-all results seem to be better than those of interlaminar approaches.

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A Prospective, Randomized Study Comparing the Results of Open Discectomy with Those of Video-Assisted Arthroscopic Microdiscectomy*†

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Abstract

Background: **The usefulness of video-assisted arthroscopic microdiscectomy for the treatment of a herniated lumbar disc has been studied previously. In the current prospective, randomized study, the results of this procedure were compared with those of conventional open laminotomy and discectomy.**

Methods: **Sixty patients who had objective evidence of a single intracanalicular herniation of a lumbar disc caudad to the first lumbar vertebra were randomized into two groups consisting of thirty patients each; Group 1 was managed with open laminotomy and discectomy, and Group 2 was managed with video-assisted arthroscopic microdiscectomy. None of the patients had had a previous operation on the low back, and all had failed to respond to nonoperative measures. Analysis of the outcomes of both procedures was based on the patient's self-evaluation before and after the operation, the preoperative and postoperative clinical findings, and the patient's ability to return to a functional status. The patients were followed for nineteen to forty-two months postoperatively.**

Results: **On the basis of the patient's preoperative and postoperative self-evaluation, the findings on physical examination, and the patient's ability to return to work or to normal activity, twenty-eight patients (93 percent) in Group 1 and twenty-nine patients (97 percent) in Group 2 were considered to have had a satisfactory outcome. The mean duration of postoperative disability before the patients were able to return to work was considerably longer in Group 1 than in Group 2 (forty-nine compared with twenty-seven days). The patients in Group 1 used narcotics for a longer duration postoperatively. No neurovascular complications or infections were encountered in either group.**

Conclusions: **Although the rate of satisfactory outcomes was approximately the same in both groups, the patients who had had an arthroscopic microdiscectomy had a shorter duration of postoperative disability and used narcotics for a shorter period. These findings suggest that arthroscopic microdiscectomy may be useful for the operative treatment of specific symptoms, including radiculopathy, that are caused by lumbar disc herniation, provided that patients are properly selected — that is, they must have a herniated disc at a single level as confirmed on imaging studies, have failed to respond to nonoperative management, have no evidence of spinal stenosis, and have a herniation not exceeding one-half of the anteroposterior diameter of the spinal canal. Moreover, the surgeon must be familiar with this technique and must have received training in its use.**

The concept of an indirect, extracanalicular approach to the intervertebral discs is not new. In the early 1950s, Hult[8] proposed an anterior retroperitoneal approach. In the early 1960s, Smith et al.[29] introduced the concept of chemonucleolysis. Subsequently, the posterolateral paramedial approach was used for manual nucleotomy[5,9,14]. This was followed by the introduction of small-caliber automated instruments for decompression and extraction of the nuclear tissue[20]. However, recent prospective, randomized studies have cast doubt on the efficacy of nuclear debulking procedures for the treatment of symptom-producing lumbar disc herniations[25].

The evolution from blind manual posterolateral discectomy to endoscopic or arthroscopic extraction of disc fragments in the late 1980s became feasible because of technological advances and the availability of small-caliber, high-resolution glass fiberoptics that enabled the operating surgeon to visually differentiate anatomically normal from abnormal periannular and intracanalicular structures[12,14]. Subsequent studies in cadavera not only made it possible to identify a safe zone on the dorsolateral corner of the annulus where the instruments could be positioned but also permitted a description of the zone's radiographic landmarks[11,12,14,19].

Various authors have investigated the long-term outcomes of arthroscopic microdiscectomy[1,12,13,15,17,18,22,27,28]. The purpose of the current study was to evaluate pro-

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†Read in part at the Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, Louisiana, March 23, 1998.

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TABLE I
DEMOGRAPHIC DATA

	Group 1: Laminotomy and Discectomy (N = 30)	Group 2: Arthroscopic Microdiscectomy (N = 30)
Male:female ratio	17:13	22:8
Age* *(yrs.)*	40 (18-67)	39 (15-66)
Operative level		
L2-L3	0	1
L3-L4	1	6
L4-L5	23	19
L5-S1	6	4
Mean preop. level of pain *(points)*	6.6	6.8
Preop. objective findings *(no. of patients)*		
Positive tension signs	30	30
Matching imaging studies	30	30
Reflex abnormalities	9	12
Sensory deficits	28	26
Motor weakness	26	24

*The values are given as the mean, with the range in parentheses.

spectively the results of arthroscopic posterolateral discectomy compared with those of open discectomy and laminotomy with regard to the patient's postoperative subjective evaluation of low-back pain and radicular symptoms, the objective physical findings, the duration of disability, and the use of or need for pain medication.

Materials and Methods

Sixty patients met the criteria for enrollment in the study, as established by physical examination and confirmed with imaging studies and by the symptoms. These criteria consisted of a single intracanalicular disc herniation at the level between the second and third, the third and fourth, or the fourth and fifth lumbar vertebrae or between the fifth lumbar vertebra and the first sacral segment, with associated radiculopathy; a herniation not exceeding one-half of the anteroposterior diameter of the spinal canal; an absence of central or lateral osseous or ligamentous stenosis; accessibility of the disc for both arthroscopic microdiscectomy and laminotomy; failure to respond to nonoperative measures; more pain in the lower extremities than in the back; the presence of positive tension signs with or without an accompanying neurological deficit; a dermatomal distribution of pain in the lower extremities matching that seen on imaging studies and specific nerve-root involvement; no previous operation on the low back; and the absence of any litigation or Workers' Compensation claim involving the disc herniation.

The criteria for exclusion from the study included central or lateral stenosis of the spinal canal; severe degenerative narrowing of the intervertebral disc space at the index level; evidence, on imaging, of global bulging of the intervertebral disc[10] associated with central or lateral stenosis; a sequestered herniation that had migrated; a large central or extraligamentous herniation between the fifth lumbar and first sacral vertebrae; drug dependency; and known psychological disorders.

The study comprised sixty patients: thirty who had an open laminotomy and discectomy (Group 1) and thirty who had a video-assisted arthroscopic microdiscectomy (Group 2). The ages of the seventeen male and thirteen female patients in Group 1 ranged from eighteen to sixty-seven years (mean, forty years), whereas those of the twenty-two male and eight female patients in Group 2 ranged from fifteen to sixty-six years (mean, thirty-nine years). Forty-four (73 percent) of the sixty patients were between the ages of twenty-five and fifty years.

The open laminotomy and discectomy (Group 1) was performed between the third and fourth lumbar vertebrae in one patient, between the fourth and fifth lumbar vertebrae in twenty-three patients, and between the fifth lumbar and first sacral vertebrae in six patients (Table I). The arthroscopic microdiscectomy (Group 2) was performed between the second and third lumbar vertebrae in one patient, between the third and fourth lumbar vertebrae in six patients, between the fourth and fifth lumbar vertebrae in nineteen patients, and between the fifth lumbar and first sacral vertebrae in four patients (Table I).

Although spinal stenosis is the most common cause of lumbar radiculopathy in elderly patients, the patients in this study did not have clinical or imaging characteristics of spinal stenosis, and they met the criteria for inclusion mentioned earlier.

All sixty patients had been managed nonoperatively elsewhere and were referred to our institution for consideration of operative management. However, when the nonoperative measures appeared to have been suboptimum, additional nonoperative treatment was employed. Because of the methods that were used, no data are available on the percentage of patients who responded to nonoperative therapy. The minimum duration of nonoperative treatment in both groups was fourteen weeks. None of these patients had worsening of the neurological deficit, which would have necessitated earlier operative intervention. In addition to the nonoperative treatment, nine patients in Group 1 (open laminotomy and discectomy) and twelve patients in Group 2 (arthroscopic microdiscectomy) had received steroids orally, and seven patients in each group had received epidural injections of steroids before being referred to our clinic.

The herniation had penetrated the boundary of the posterior longitudinal ligament in four patients in Group 1 and in five patients in Group 2. The herniated disc fragments were retrieved successfully from all patients. None of these herniations were displaced cephalad or caudad.

The nonoperative measures included short-term partial rest with avoidance of lifting, bending, climbing,

TABLE II
POSTOPERATIVE FINDINGS

	Group 1: Laminotomy and Discectomy (N = 30)	Group 2: Arthroscopic Microdiscectomy (N = 30)
Mean age *(yrs.)*	40	39
Duration of disability *(days)*	49	27
Mean pain score* *(points)*	1.9	1.2
Mean score for frequency of postop. use of narcotics† *(points)*	2	1
No. of patients who were "very satisfied" with operative result	20 (67%)	22 (73%)

*On a scale of 0 to 10 points.
†On a scale of 1 to 5 points.

or long periods of standing or sitting. All patients received nonsteroidal anti-inflammatory medication for approximately six weeks and participated in a standard physical therapy and exercise program before the operative procedure. Nonoperative management was considered to have failed in patients who had persistent or recurrent radicular symptoms in a specific dermatomal distribution, with pain in the lower extremities that was more disabling than pain in the low back; those who had positive tension signs (a positive straight-leg-raising test with the patient supine, a positive Lasègue sign, and a positive straight-leg-raising test with the patient seated); and those who had unremitting pain and a neurological deficit.

Neurological findings included reflex abnormalities in nine patients in Group 1 (open laminotomy and discectomy) and in twelve in Group 2 (arthroscopic microdiscectomy). These abnormalities included a unilateral absence of the tibialis posterior reflex, observed in three patients who had a disc herniation between the fourth and fifth lumbar vertebrae. In addition, twenty-eight patients in Group 1 and twenty-six in Group 2 had sensory deficits, and twenty-six in Group 1 and twenty-four in Group 2 had motor weakness (Table I).

The imaging studies were reviewed carefully by radiologists and the operating surgeon. An intervertebral disc was considered to be herniated when there was evidence of localized expansion of the external contour of the disc that was effacing the nerve root or the dural sac[1,17].

Sixty sealed envelopes containing the words arthroscopic microdiscectomy or laminotomy were prepared and randomly placed in the files of patients who had lumbar radiculopathy that potentially necessitated operative intervention. This was done by the clinic's office personnel at the time of the first interview. If the examining physician thought that the patient was not a candidate for operative treatment, the envelope was removed and was returned to the secretarial area for future use. Before the operation, the envelope was obtained from the patient's chart for the selection of either arthroscopic microdiscectomy or laminotomy and discectomy.

The study was not blinded because of legal restrictions imposed by the *patient's right to know* and the fact that, postoperatively, the size and site of the skin incision alerted the patient to the nature of the operative procedure. The advantages and disadvantages of arthroscopic microdiscectomy compared with laminotomy and discectomy and with nuclear debulking procedures were carefully reviewed with the patients and their families. Appropriate consent, the wording of which was approved by the institutional review board, was obtained, and the procedure was performed in the operating suite.

Patients who had been referred for a specific operative procedure and those who insisted on having either a laminotomy or an arthroscopic microdiscectomy were excluded from the study. The envelope was then re-

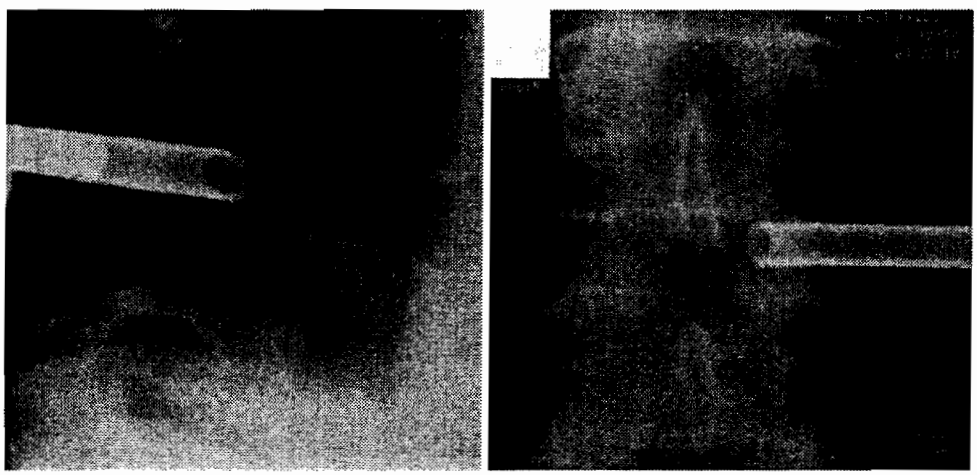

FIG. 1-A FIG. 1-B

Lateral (Fig. 1-A) and anteroposterior (Fig. 1-B) intraoperative fluoroscopic images demonstrating the positioning of an oval cannula in the triangular working zone between the traversing and exiting nerve roots on the dorsolateral corner of the intervertebral disc. The cannula is engaged and stabilized in the superficial layers of the annulus.

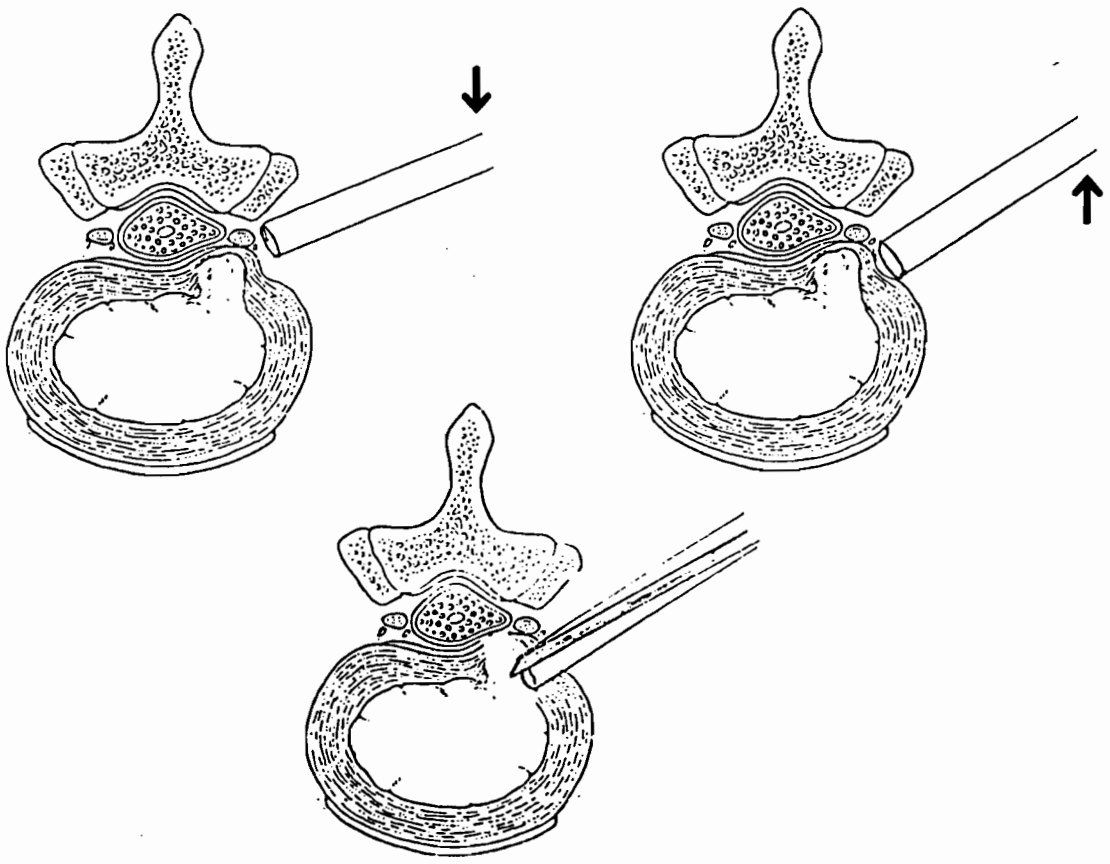

FIG. 2

Schematic drawings showing the operative technique. *Top left:* The external end of the cannula is tilted anteriorly, thus rotating the tip posteriorly for inspection and localization of the contents of the spinal canal. *Top right:* The external end of the cannula then is tilted posteriorly, thus rotating the tip anteriorly, and the cannula is held firmly against the annulus in preparation for an annulotomy adjacent to the spinal canal. *Bottom:* A 30 or 70-degree arthroscope is used for final inspection of the operative site, the anterior surface of the dural sac, and the fibers of the posterior longitudinal ligament in a contained subligamentous herniation.

turned to the secretarial area and was placed randomly in a new patient file.

Operative Technique

The open laminotomy and discectomy was performed in a standard fashion. A four-centimeter posterior midline incision was made, and a small laminotomy and discectomy was performed at the specified level. The arthroscopic microdiscectomy was performed with use of an oval five by eight-millimeter (internal diameter) cannula (Figs. 1-A and 1-B), introduced into the triangular working zone as described previously by one of us (P. K.) and colleagues[15-17]. Under anteroposterior and lateral fluoroscopic control, an 18-gauge needle was introduced in an anteromedial direction from a distance of about eleven centimeters lateral to the midline. The tip of the needle was positioned in the triangular working zone that is bordered anterolaterally by the exiting nerve root, medially by the traversing nerve root and the dura, and caudally by the vertebral plate of the caudad lumbar segment. This was followed by the introduction of a soft-tissue dilator and the positioning of a universal five-millimeter (internal diameter) cannula. The annular surface in the triangular working zone and the contents of the spinal canal were inspected through a 0-degree working channel arthroscope to ensure that the annulotomy was performed adjacent to the spinal canal, just under the posterior longitudinal ligament (Figs. 2 [top left and right] and 3). (The working channel arthroscope is a specially designed endoscope that has a separate channel for introduction of instruments such as forceps, a knife, or a curet. It also provides channels for introduction and retrieval of saline solution during the operation. The whole unit fits inside the cannula.) The conversion of the universal cannula to an oval cannula was then accomplished by the introduction of a half-moon-shaped soft-tissue dilator next to the previously positioned universal soft-tissue dilator. This permitted the smooth passage of the oval cannula into the triangular working zone and the subligamentous region of the intervertebral disc at the index level.

The oval cannula is shaped so that it fits within the boundaries of the triangular working zone between the traversing and exiting nerve roots. This permits the simultaneous insertion of a 0-degree or 30-degree discoscope and an upbiting forceps for visualization and removal of the compressive elements. In contrast to the laminotomy and discectomy, with arthroscopic micro-

discectomy the herniated disc fragments are pulled back into the intervertebral disc space and then are withdrawn. The anterior aspect of the dura or the fibers of the posterior longitudinal ligament may be inspected with a 30 or 70-degree arthroscope at the end of the procedure (Fig. 2 [bottom]).

Two patients who had evidence of a large central extraligamentous herniation that had not migrated needed a biportal access for the retrieval of herniated disc fragments.

The arthroscopic microdiscectomy was performed on an outpatient basis, whereas the laminotomy and discectomy necessitated one night of hospitalization. Hospitalized patients received no physical therapy, and they were discharged when they were able to walk without assistance.

Evaluation of the Patients

Follow-up visits were scheduled for both groups at two weeks, three months, six months, one year, and two years postoperatively.

The outcome analysis was based on the patient's self-evaluation before and after the procedure, the preoperative and postoperative findings on physical examination, and the patient's ability to return to a functional status[6,31]. Preoperatively, the patients completed a two-page questionnaire (a modification of the Rush-Presbyterian-St. Luke's lumbar spine analysis form[31]) that included information regarding symptoms (the presence or absence of numbness or weakness, the status and duration of disability, the types and dosages of medications and their frequency of use, the patient's ability to work, and diagrams showing the dermatomal distribution of the pain). The patients rated pain with use of the method of Houde[6]. The postoperative evaluation consisted of physical examination by an independent physician as well as questionnaires that focused on patient satisfaction, pain and use of pain medications, weakness and numbness, disability, the duration until the patient was able to return to work or to normal activity, and the patient's ability to work.

Results

The mean duration of follow-up was thirty-one months (range, nineteen to forty-two months) for the patients in Group 1 (open laminotomy and discectomy) and thirty-two months (range, twenty-one to forty-two months) for the patients in Group 2 (arthroscopic microdiscectomy).

The postoperative management in Group 1 included intravenous patient-controlled administration of morphine sulfate for twenty-four hours. This was followed by oral administration of Percocet (oxycodone hydrochloride and acetaminophen). The mean duration of use of narcotics in this group was twenty-five days (range, seven to fifty-six days). In addition, at the time of the latest follow-up evaluation, six patients (20 percent) reported occasional use of codeine derivatives for control of the low-back pain or the pain in the buttocks, or both.

The patients in Group 2 did not need injectable medications postoperatively, and the mean duration of use of orally administered narcotics was seven days (range, three to fourteen days).

The mean duration of postoperative disability — that is, the time lost from work or until the patient was able to resume normal activity — was forty-nine days in Group 1 (Table II); this group included two retired individuals, two students, and two homemakers who resumed their normal activities. In Group 2, a mean of twenty-seven days was lost; this group included one student and one homemaker who returned to their preoperative daily activities. It also included one patient who had been receiving disability compensation preoperatively because of a reason unrelated to the disc herniation, and this patient remained disabled after the operative procedure. A patient in Group 1 had leakage of spinal fluid, which necessitated exploration and repair of the dural sac two weeks postoperatively. This patient had a long period of postoperative disability with satisfactory closure of the dural leak, but there was residual disability associated with pain in the low back and buttocks. Another Group-1 patient continued to have radicular symptoms and was considered to have had failure of the operative procedure. One patient in Group 2 later needed a two-level laminotomy and partial facetectomy for the treatment of mild lateral stenosis that had not been recognized at the time of the index operation. Postoperative complications such as infection or neurovascular injuries were not observed in either group of patients.

The postoperative findings on physical examination included reflex abnormalities in six patients in Group 1 and in seven patients in Group 2. Sensory deficits were found in eighteen patients in Group 1 and in sixteen

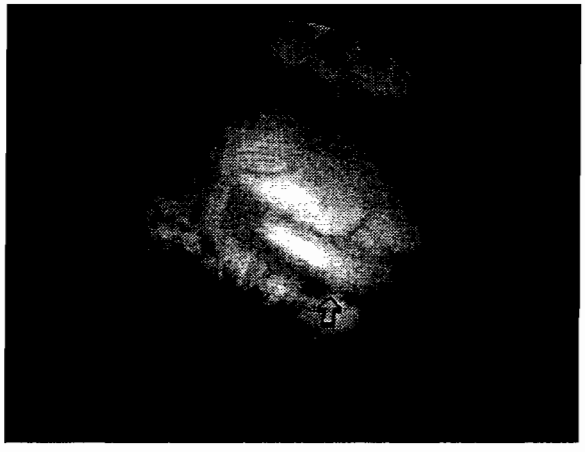

FIG. 3

The endoscopic appearance of an inflamed nerve root (top) at the fifth lumbar level. Note the superficial vessels on the surface of the nerve root. The lateral boundary of a paramedial disc herniation (arrow) is visible under the nerve root.

patients in Group 2. Motor weakness was detected in ten patients in Group 1 and in five patients in Group 2. All patients who had a satisfactory outcome had negative postoperative tension signs.

The outcome was considered to be excellent if the radicular symptoms had ceased, the tension signs had become negative, the patient had returned to his or her previous occupation or to normal activity, and the patient expressed satisfaction with the result of the operative procedure. The outcome was considered to be good if the criteria just mentioned were met but the patient had residual back pain and had had to modify his or her occupation. The operation was considered to have failed if the patient had persistent radicular symptoms or needed an additional operative procedure. An excellent or good result was considered a satisfactory outcome. On the basis of the patient's preoperative and postoperative self-evaluation, the findings on physical examination, and the patient's ability to return to work or to normal activity, twenty-eight patients (93 percent) in Group 1 (open laminotomy and discectomy) and twenty-nine patients (97 percent) in Group 2 (arthroscopic microdiscectomy) were considered to have a satisfactory outcome.

The postoperative questionnaire included a 4-point satisfaction scale, with 1 point indicating that the patient was very satisfied with the outcome of the operation; 2 points, that the patient was satisfied; 3 points, that the patient was dissatisfied; and 4 points, that the patient was very dissatisfied. Twenty patients (67 percent) in Group 1 and twenty-two patients (73 percent) in Group 2 reported that they were very satisfied with the outcome. The patients also rated pain, with use of a 10-point scale, with 0 points indicating that they were pain-free and 10 points indicating that they had severe and incapacitating pain. The mean postoperative pain score was 1.9 points for Group 1 and 1.2 points for Group II (Table II).

Discussion

The patient populations in the two groups were similar. In most of the patients, the herniated disc was between the third and fourth or the fourth and fifth lumbar segments. In Group 1 (open laminotomy and discectomy), twenty-four patients had extraction of a disc between the third and fourth or the fourth and fifth lumbar levels, whereas in Group 2 (arthroscopic microdiscectomy) twenty-five patients had the operation at one of these sites.

Although the numbers of patients who had a satisfactory outcome were similar in the two groups, the rate of postoperative morbidity was lower in the patients who had the minimally invasive, video-assisted arthroscopic microdiscectomy than in those who had the open laminotomy and discectomy. All of the arthroscopic procedures were performed on an outpatient basis, whereas the patients who had the laminotomy and discectomy needed at least one day of hospitalization. The postoperative use of narcotics was less and the overall satisfaction score was higher after the arthroscopic microdiscectomies than after the laminotomies and discectomies.

Although both macrodiscectomy and microdiscectomy are simple and acceptable methods for the treatment of a symptom-producing disc herniation, the current randomized study suggests that, for selected patients who meet specific criteria, a video-assisted arthroscopic microdiscectomy may be useful for the operative treatment of a lumbar disc herniation.

The shorter period of postoperative disability for the patients who had a video-assisted arthroscopic microdiscectomy may be attributed to the absence of the epidural fibrosis and tethering of nerve roots that are commonly observed after laminotomy and intracanalicular approaches[3,4,23,26]. In addition, the epidural venous systems[7,21] are not disturbed during video-assisted microdiscectomy. This helps to prevent the postoperative development of venous stasis and chronic nerve-root edema. The minimum operative trauma inflicted on myoligamentous structures[24,30] also may play an important role in the rapid recovery of patients after video-assisted microdiscectomy.

Arthroscopic visualization of the contents of the spinal canal in the patients in Group 2 made it possible to gain access to the herniated lumbar disc with use of a posterior subligamentous approach without entering the spinal canal[15-17]. The midpedicular placement of instruments adjacent to the spinal canal under discoscopic magnification and illumination made it possible to sweep the inserted instrument anteriorly near the traversing nerve root and the lateral aspect of the dura and to evacuate the herniated disc fragments.

Although the details of the operative technique are not within the scope of this report[12,15-17], it should be noted that most orthopaedic surgeons have some familiarity with the posterolateral approach and have used this access for bone biopsies[2] and nuclear debulking procedures[5,20,29]. In contrast, mastery of arthroscopic access to the disc fragments requires commitment and patience and cannot be learned in a short time-period. Particular attention to detail, including selection of patients with use of the criteria described earlier, preoperative planning, and operative technique, is essential to the success of this operative procedure.

During preoperative planning, a decision should be made about whether a single portal, inserted from the symptomatic side of the patient, is sufficient, or whether introduction of a second portal from the opposite side will be necessary for access and retrieval of herniated disc fragments.

Although use of an oval cannula (Figs. 1-A and 1-B) has greatly limited the need for bilateral, biportal access, the removal of a disc causing a large central herniation or one that has penetrated the boundary of the posterior longitudinal ligament requires biportal access

for intradiscal triangulation and clear visualization of herniated fragments and the anterior surface of the dural sac.

Positioning of the instruments adjacent to the spinal canal must be emphasized. Although it is advisable, at the onset of the procedure, to make a quick arthroscopic inspection of the contents of the spinal canal to ensure posterior subligamentous positioning of the annular fenestration, epidural bleeding and adipose tissue invariably obstruct proper visualization of neurovascular structures and interfere with intracanalicular procedures performed through a foraminal approach. Inspection of the contents of the spinal canal is accomplished by tilting the external end of the inserted cannula anteriorly (with the patient in a prone position) (Figs. 2 [top left] and 3). The external end of the cannula then is tilted posteriorly (Fig. 2 [top right]) and is held against the annulus in preparation for annular fenestration and retrieval of herniated disc fragments. Final inspection of the intradiscal area through a 30 or 70-degree arthroscope (Fig. 2 [bottom]) will demonstrate the exposure of the anterior aspect of the dura and the adequate retrieval of the herniated disc fragments.

The data from this randomized, prospective study suggest that, in properly selected patients who meet the criteria for inclusion described earlier, a video-assisted arthroscopic microdiscectomy may be useful for the operative treatment of a lumbar disc herniation. However, arthroscopic microdiscectomy is a demanding technique and should not be attempted without specific instruction and training. Similar studies of larger groups of patients are needed to confirm these results statistically.

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Evolving Transforaminal Endoscopic Microdecompression for Herniated Lumbar Discs and Spinal Stenosis

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ABSTRACT

The objective of this chapter was to demonstrate evolving transforaminal endoscopic microdecompression for herniated lumbar discs and spinal stenosis, and to become accomplished with endoscopic micro spinal instruments and laser application. Since 1993, 2000 patients with 3421 herniated lumbar discs were diagnosed with symptomatic lumbar single and multiple herniated intervertebral discs. Progressive series of different diameters endoscopic-assisted tubular retractors, with appropriate-sized dilators and more aggressive saw-toothed trephines, and laser were used to perform transforaminal endoscopic microdecompression, in addition to the posterior-lateral foraminoscope and endoscopic-assisted spinal operating systems. No postoperative mortalities occurred, and the morbidity rate was less than 1%, in the 2000 patients. For a single level, 94% of the patients had good or excellent results; 6% had some residual symptoms although improved overall. Transforaminal endoscopic laser microdecompression can effectively decompress herniated lumbar discs and spinal stenosis, when foraminoplasty is performed, which provides a safe and effective modality to achieve results in effective spinal decompression, preserves spinal motion, and creates a channel for spinal arthroplasty.

INTRODUCTION

Lumbar stenosis is one of the most common diseases of the spine for patients over the age of 65. Although the pathophysiology of lumbar stenosis is multifactorial with compression of neuro elements, it generally occurs from a combination of degenerative changes, including bulging discs, ligamentum flavum hypertrophy, facet thickening, and arthropathy. The classic wide posterior decompressive laminectomy with foraminotomy involves extensive muscle and soft-tissue dissection for exposure, decompression, and resection of the posterior spinal elements. Despite varying degrees of success,[1] it is associated with significant iatrogenic trauma and failed back syndrome.[1,2] As a result, the search for a minimally invasive spinal surgery (MISS) began.

With accumulated experience with endoscopically assisted mechanical and laser lumbar discectomy,[3-19] the need for a method to more effectively decompress the lateral recess[1,2,20-25] and intervertebral neural foramen from very large or extruded disc protrusions, recurrent discs, scar tissue, and spondylitic spurs became evident. The most frequently seen lumbar spinal disc disease in the elderly is spinal and lateral foraminal stenosis.[1,25] Lateral stenosis may be congenital or degenerative when secondary to acute disc disease and spinal trauma. This article describes the surgical techniques of evolving transforaminal endoscopic microdecompression for herniated lumbar discs and spinal stenosis,[11] and a minimally invasive transforaminal microdecompressive endoscopic-assisted discectomy and foraminoplasty (TF-MEAD), a new system of more aggressive mechanical instruments and laser application, developed at the California Center for Minimally Invasive Spine Surgery (C-MISS).

The pioneering work of Hijikata[3] with percutaneous manual discectomy, Ascher and Choy[4] with percutaneous laser discectomy, and the application of endoscopy by Kambin and Saliffer,[5] and others[26-31] resulted in monitored keyhole operations for removal of herniated lumbar discs. The use of endoscopy and laser, especially the Holmium side-firing laser, allows removal of large protrusions and extruded disc fragments from the epidural space and stenotic foraminal decompression.[11,28]

Currently, attention is being directed toward treatment of epidural scarring, lateral recess, foraminal stenosis, and advanced degenerative changes often bilateral and occur at multiple levels.[27] The author has developed a more aggressive TF-MEAD system to address endoscopic transforaminal mechanical and laser microdecompressive discectomy and foraminoplasty in a fast and effective manner for both unilateral single and bilateral multiple levels. These MISS procedures should now be added to the choice of interventions of the spinal surgeon in treating advanced degenerative spinal stenosis and lateral foraminal stenosis.

Such procedures require the surgeon to be knowledgeable and competent in MISS, with thorough knowledge of the procedure of endoscopic lumbar discectomy and foraminoplasty, patho-anatomy of the neuro-foramen and spine, relationships of the lumbar exiting and traversing nerve roots, dorsal root ganglion, the facet joint, disc, and vertebrae.

INDICATIONS

Endoscopic lumbar foraminoplasty is indicated in the following clinical situations:[11-17]

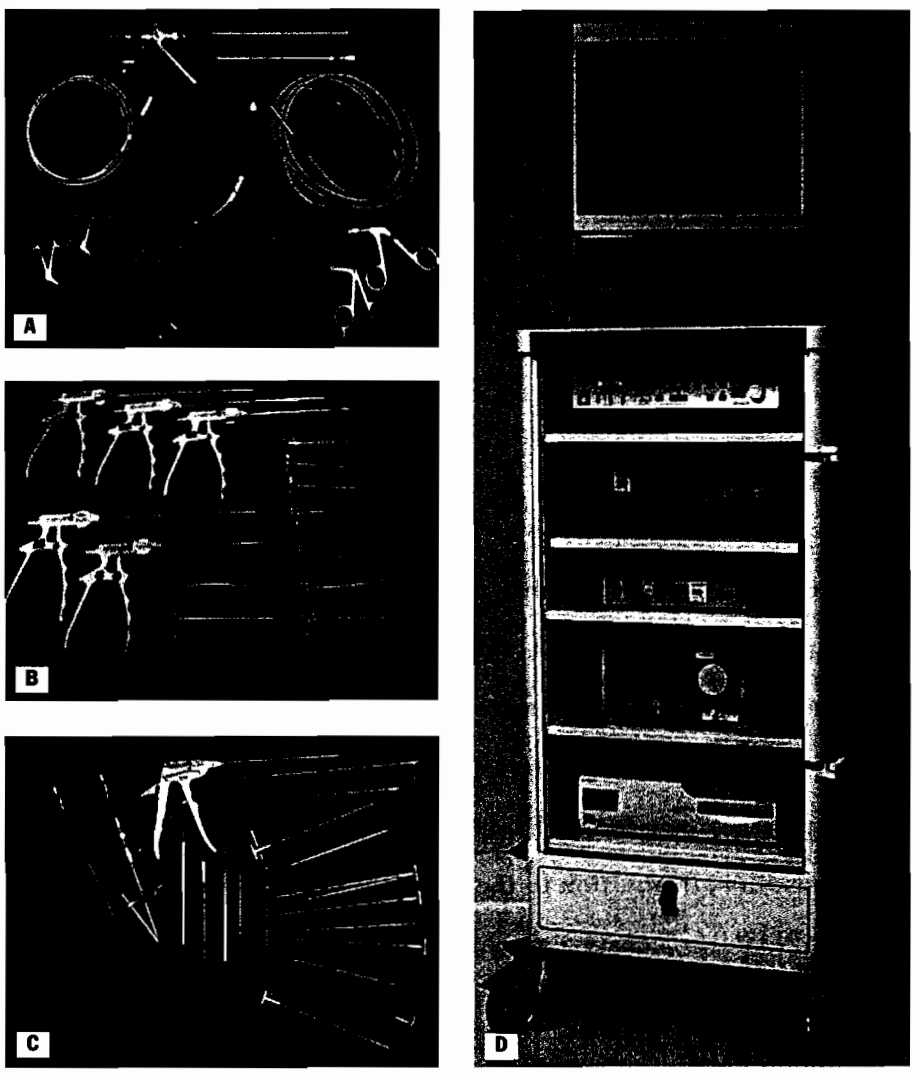


Figure 1. Surgical instruments for Endoscopic Lumbar Foraminoplasty and Discectomy. (A) Percutaneous fiberoptic foraminoscope 0 degrees, 6-mm OD, 3.9-mm working channel (w.c.); Posteriorlateral foraminoscope 6 degrees, 3-mm w.c. (Karl Storz Endoscopy America, Inc., Culver City, CA), bare holmium laser fiber, side-firing laser probe (Trimedyne), and discectomy forceps. (B) C-MISS TF-MEAD transforaminal decompressive system: endoscopes (0 and 30 degree, 4-mm OD) assisted tubular retractor, 9.9 mm, trephine, graduated duck bill cannulae, trephine, discectomy rongeur, curette, and 2-mm bone punch. (C) Lumbar discectomy set with dilators, working cannulae, trephines, and various discectomes.

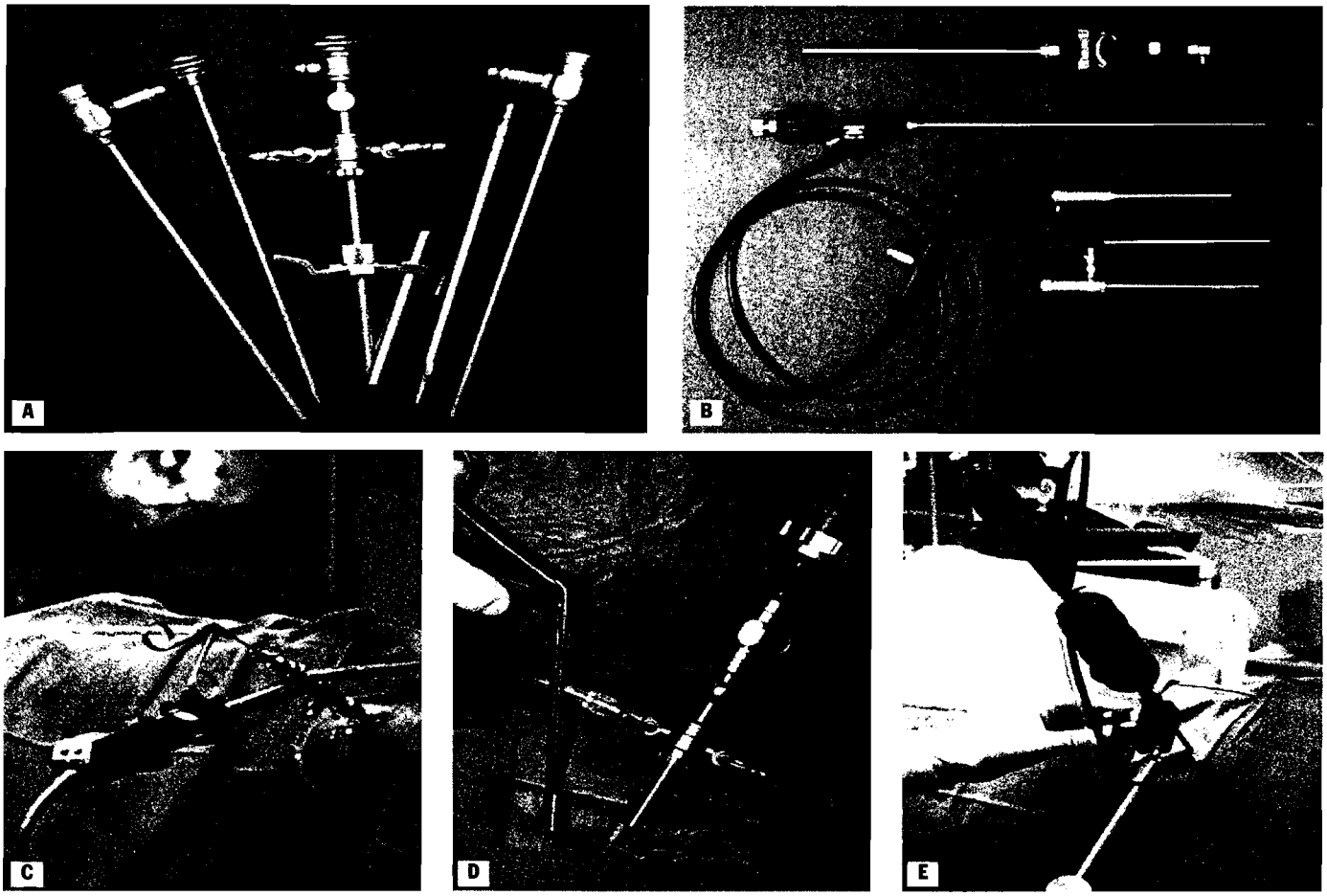


Figure 2. Steerable Spinoscope system, C-MISS TF-MEAD system, and foraminoscope for treatment of disc herniation and foramen stenosis. (A) Spinoscope surgical application for TF-MEAD. (B) Steerable Spinoscope and cannular set for laser application and with flexible tip (Karl Storz Endoscopy America, Inc. Culver City, CA). (C) Posterolateral foraminoscopy with wide angle 6-degree 3-mm w.c. operating foraminoscope (Karl Storz Endoscopy America, Inc., Culver City, CA). (D) C-MISS TF-MEAD system with a working channel 9.9 mm assisted by endoscopes (0 and 30 degrees, 4-mm OD). (E) Lumbar foraminoplasty with C-MISS TF-MEAD system in surgical application.

- ◆Intractable low back pain with radiation down the leg (radicular pain).
- ◆Symptoms of spinal neurogenic claudication.
- ◆Compressive and irritative radiculopathy with sensorimotor impairment.
- ◆Disc extrusion or sequestration with predominantly back or leg pain.
- ◆Degeneration and settlement of the spine with predominantly back, buttock, or leg pain.
- ◆Non-radicular low back pain persisting despite facet joint injection.
- ◆Lateral recess stenosis with dynamic compressive or non-compressive radiculopathy.
- ◆Prior failed conventional surgery with perineural scarring and failed back syndrome.
- ◆No improvement of symptoms after a minimum of 12 weeks of conservative therapy.
- ◆Spondylolytic spondylolisthesis.
- ◆Diagnostic imaging, MRI, CT, CT 3D, CT Myelogram, that demonstrate disc herniation, extrusion, or both, or lateral recess stenosis.
- ◆Positive pre- or intraoperative discogram and pain provocation test.
- ◆Positive electromyography is considered helpful.
- ◆Multiple lumbar discs/levels can be treated at one sitting with TF-MEAD.

CONTRADICTIONS

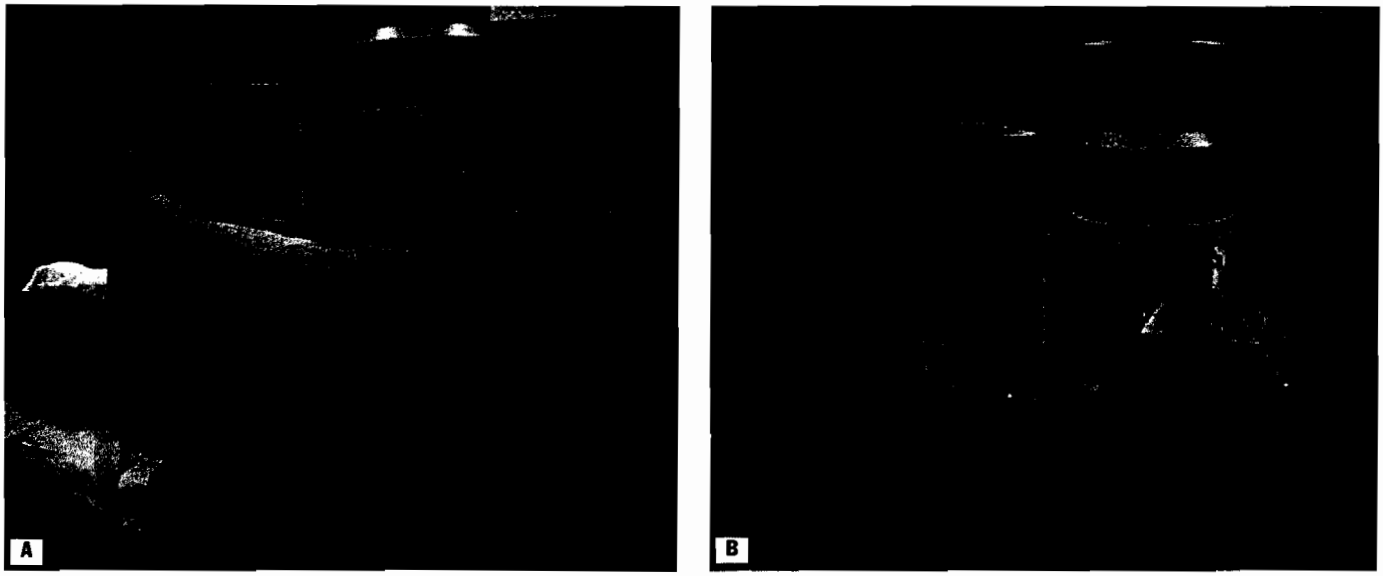
The endoscopic lumbar foraminoplasty procedure is contraindicated in the following clinical situations:[11,17]

- ◆Cauda equina syndrome.
- ◆Painless motor deficit.
- ◆Tumors.
- ◆Clinical findings that suggest pathology other than degenerative discogenic disease.

INSTRUMENTS AND PREPARATIONS

These surgical instruments are necessary to perform endoscopic laser, lumbar foraminoplasty, or both:

- ◆Digital fluoroscopic equipment (C-arm) and monitor.
- ◆Radiolucent C-arm/fluoroscopic carbon-fiber surgical table.
- ◆Endoscopic tower equipped with digital video monitor, DVT/VHS recorder, light source, tri-chip digital camera, and photo printer system.
- ◆Percutaneous fiber optic foraminoscope 0-degree 6-mm OD, 3.9-mm working channel (Karl Storz Endoscopy America, Inc., Culver City, CA) (Fig. 1).
- ◆Wide-angle percutaneous posterolateral foraminoscope 6-degree, operating sheath 6-mm OD, 3-mm working channel (Karl Storz Endoscopy America, Inc., Culver City, CA; see Fig. 1).
- ◆C-MISS TF-MEAD system-instruments (see Fig. 1).
- ◆Set of serial/progressive dilators, and cannulae in graduated sizes (3.5-5.8 mm); a set of progressive cannulae with duck bill extensions (with various lengths 5-10 mm on one side) (see Fig. 1).



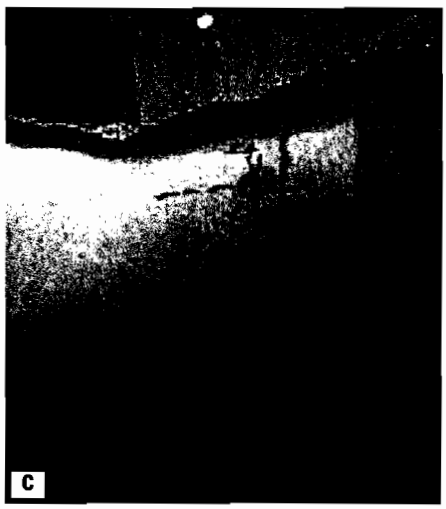


Figure 3. Patient positioning and localization. (A) Patient in lateral decubitus position. (B) Patient in prone position. (C) Localization—skin marking and placement of needle (portal).

- ◆Aggressive toothed trephine set in graduated sizes.
- ◆9.9-mm tubular retractor system with a gradual dilator set.
- ◆Wide angle endoscopes, 0-degree and 30-degree, 4-mm OD (Karl Storz Endoscopy America, Inc., Culver City, CA).
- ◆Trephine, curette, grasper and spoon forceps, 2-mm rotating bone punch (rongeurs), rasp, and bur.
- ◆Lumbar discectomy sets (2.5, 3.5, 4.7 mm) (Blackstone Medical, Inc., Springfield, MA, USA) with various discectomies (see Fig. 1).
- ◆Endoscopic grasping and cutting forceps, probe, knife, scissors, discectomy rongeurs, and curette (see Fig. 1).
- ◆Holmium: yttrium aluminum garnet (YAG) laser generator (Trimedyne, Irvine, CA, USA).
- ◆Holmium 550-μm laser bare fiber with flat tip and right angle (side-firing) probes with and without irrigating system of various sizes, and (see Fig. 1) 2-mm side-firing irrigating laser probe.
- ◆Steerable Spinoscope (Karl Storz Endoscopy America, Inc., Culver City, CA) (Fig. 2) with 2.5-mm working fiberscope (for laser application with a flexible tip that can bend up to 90 degrees and rotate to reach 360 degrees).

ANESTHESIA

The patients are treated in an operating room under local anesthesia and monitored conscious sedation. The Anesthesiologist maintains mild sedation, but the patient is able to respond. Two Grams Cefazolin and 8 mg dexamethasone are given intravenously at the start of anesthesia. Surface EEG (SNAP™, Nicolet Biomedical, Madison, WI, USA) monitoring provides added precision of anesthesia.

PATIENT POSITIONING

For this procedure, if surgery is unilateral the patient is placed in a lateral decubitus position (Fig. 3) with the painful leg up and both hips and knees in moderate flexion. If the patient has an increased medical risk (ie, pulmonary, cardiac, morbid obesity, and other high-risk medical conditions, but requires a bilateral procedure), the decubitus position may be used first on one side, and then, turning the patient over, on the other side, to perform the bilateral procedure in one sitting. Otherwise, bilateral operations are performed in the prone position on a radiolucent support similar to the Wilson frame. The arms are supported on arm boards over the head. When local anesthesia and mild sedation are used, the extremities, buttocks, and shoulders are secured and restrained from sudden motion with adhesive tape.

LOCALISATION

C-arm fluoroscopy is used to identify the lumbar levels relative to the sacrum. The midline, operative levels, and point of entry (operating portal) (Figs. 3 & 4) for surgery are marked on the skin with a marking pen. The distance of the point of entry from the midline varies with the height and weight of the patient, but for an average-size patient is approximately 12 cm at the affected disc level. Positioning of the instruments is checked throughout the procedure by fluoroscopy in two planes (Figs. 5-8) as often as needed. At the involved nerve roots distribution, sterile needle electrodes are placed for continuous intraoperative neurophysiological electromyogram (EMG) monitoring.[29]

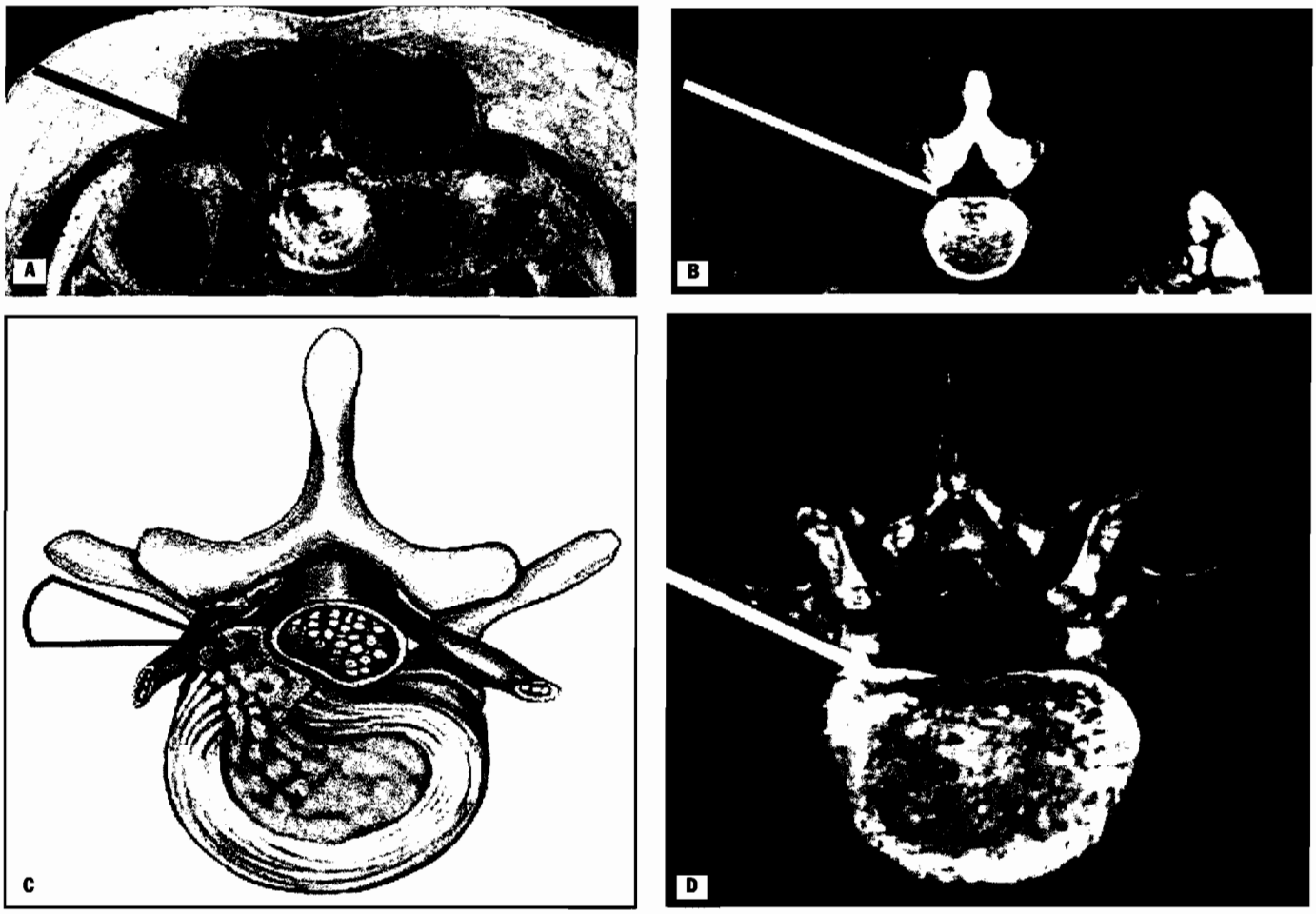


Figure 4. Safe surgical approach to neuro foramen for endoscopic lumbar foraminoplasty and discectomy. (A) Posteriorlateral surgical approach to lumbar disc in cadaveric axial cryomicrotome. (B) Posterolateral surgical approach on prone axial CT image at lumbar disc level. (C) Axial illustration of posterior-lateral lumbar surgical approach for needle placement into intervertebral foramen. (D) Posterolateral surgical approach into the foramen on axial view of lumbar spine 3D CT image.

SURGICAL TECHNIQUE FOR TRANSFORAMINAL ENDOSCOPIC MICRODECOMPRESSION FOR HERNIATED LUMBAR DISCS AND SPINAL STENOSIS AND FORAMINOPLASTY

If a pain provocation test and discogram were not done preoperatively, they are done at the outset. If the discogram and pain provocation tests are confirmatory, surgery is performed (see Figs. 2, 4, 5, & 7). An 18-gauge stylette is inserted and advanced incrementally under C-arm fluoroscopic guidance in two planes, at a 55- to 60-degree angle from the sagittal plane, targeting toward the center of the disc, through the safety zone, into the desired interspace. All instrumentation is performed under C-arm fluoroscopic control and endoscopy. The usual procedure for MISS is followed.[17] The appropriate size cannula and dilator are passed over the stylette to the annulus. Under fluoroscopy, the extended side of this cannula is turned to face the nerve root so as to retract and protect it.

The cannula retractors have variously shaped extensions like a duck's bill (with various lengths 5-10 mm on one side; see Figs. 1 & 5) to retract and protect the nerve root after the cannula is inserted through the foramen into the epidural space and the extension is oriented properly toward the root. The larger, more aggressively toothed trephines (see Fig. 5) are then inserted and rotated to cut through annulus, disc protrusion, spur, or spondylitic bar. The cannula is large enough to admit a slim punch (rongeur), spinal disc forceps, or pituitary forceps and full-size curettes to aid decompression of the foramen and lateral recess (see Fig. 5). An endoscope can be passed through it instead of the endoscope's sheath to facilitate mechanical and laser decompression, foraminoplasty, and discectomy. The endoscope is useful in TF-MEAD surgery for decompression in the lateral recess and peri-foraminal area. Biting forceps, discectome, and Holmium laser with continuous irrigation are used consecutively to perform intradiscal discectomy; lower-energy, non-ablative laser is applied for shrinking and tightening of the disc (laser thermodiskoplasty).[17,18]

The decompression area can be enlarged with a larger cannula retractor/trephine set. Usually, a small amount of bleeding can be controlled with cold saline irrigation and rarely requires hemostasis by laser or bi-polar coagulation. Holmium: YAG laser with a side-firing probe or 550-μm Holmium laser bare fiber (see Fig. 1) is used to ablate the disc and shrink and contract the disc, reducing the profile of protrusion and hardening the disc tissue (ie, laser thermodiskoplasty)(Table I) Disc removal is aided by a rocking excursion of the cannula in a 25-degree arc, a "fan sweep maneuver"[17,19] from side to side, that creates an inverted oval cone-shaped area of removed disc totaling up

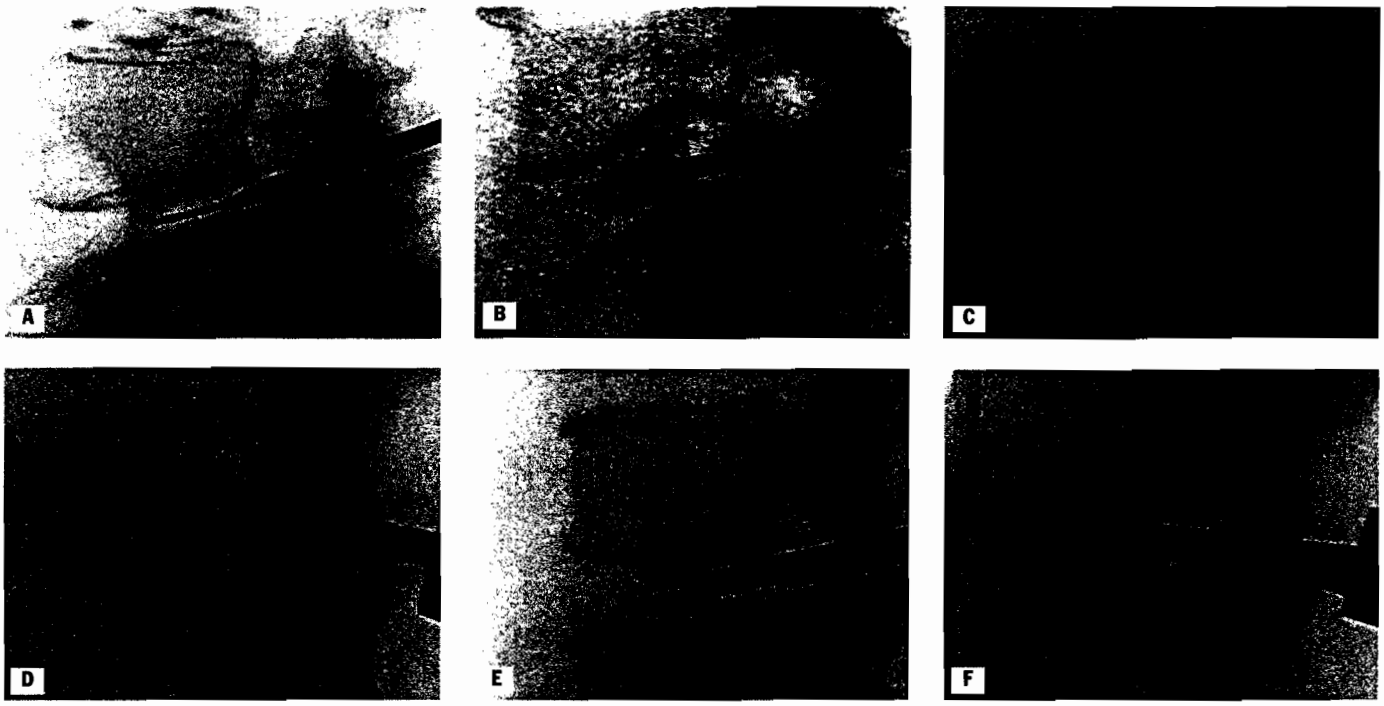


Figure 5. Fluoroscopic view of lumbar endoscopic foraminoplasty and discectomy with TF-MEAD system. (A) Stylette and dilator in disc space. (B) Trephine for disc and osteophyte decompression. (C) Discectomy forceps/rongeur for discectomy. (D) Bone punch for foraminoplasty. (E) Large discectomy rongeur through duckbill cannula retractor for discectomy. (F) Duckbill cannula and bone punch in action through TF-MEAD tubular retractor for foraminoplasty.

to 50 degrees. Laser thermodiskoplasty also can cause sino-vertebral neurolysis or denervation. The discectome is again used to remove charred debris from use of the laser.

The disc space and neural foramen can be directly visualized and examined by endoscopy to confirm adequate disc decompression and perform further decompression if necessary. If the foramen is compromised, the depth of insertion of the endoscope is adjusted, nerve root again protected by the duck bill extension, and spurs removed with curettes, bone punches (rongeurs), and Kerrison rongeurs that can be passed through the large cannula for decompressive foraminoplasty, or with laser application. Recently, an endoscopically assisted larger 9.9-mm tubular retractor system (see Figs. 1, 2, & 5) was added to facilitate foraminoplasty.

The steerable Spinoscope (Karl Storz Endoscopy America, Inc., Culver City, CA) also can be used to perform intradiscal lumbar laser discectomy and laser foraminoplasty (see Figs. 2, 7, & 9). The Spinoscope is fixed in a holding device, which allows the surgeon to guide and steer precisely a flexible fiberscope and working channel for a laser fiber of 0.6-mm diameter to the pathologic part of the disc and intra- and peri-foraminal tissue. The laser fiber can be advanced or retracted mm by mm inside the disc under direct vision with the fiber optic endoscopic system, within a given distance. Also, the tip of the applicator/laser fiber can be navigated and angulated from 0 degrees to 90 degrees, with fine adjustment, and rotated through 360 degrees in all directions.

After removing all instruments, 0.25% Marcaine is injected intradermally and into the incision and paraspinal muscles along the path of the cannulation to prolong analgesia. A band-aid is applied at the incision sites.

Table I
Laser Setting for Lumbar Disc-Laser Thermodiskoplasty

Laser Energy Used—At 10 Hz—5 Seconds On and 5 Seconds Off for TF-MEAD

	Stage	Watts	Joules
Lumbar	First Stage	15	1000
Lumbar	Second Stage	10	500

POSTOPERATIVE CARE

Ambulation begins immediately after recovery, and the patient is usually discharged one hour after surgery. They may shower the following day. Applying an ice pack is helpful. Nonsteroidal anti-inflammatory drugs (NSAIDs) are prescribed, and mild analgesics and muscle relaxants as needed. Patients return to usual activities in ten days to three weeks, provided heavy labor and prolonged sitting are not involved.

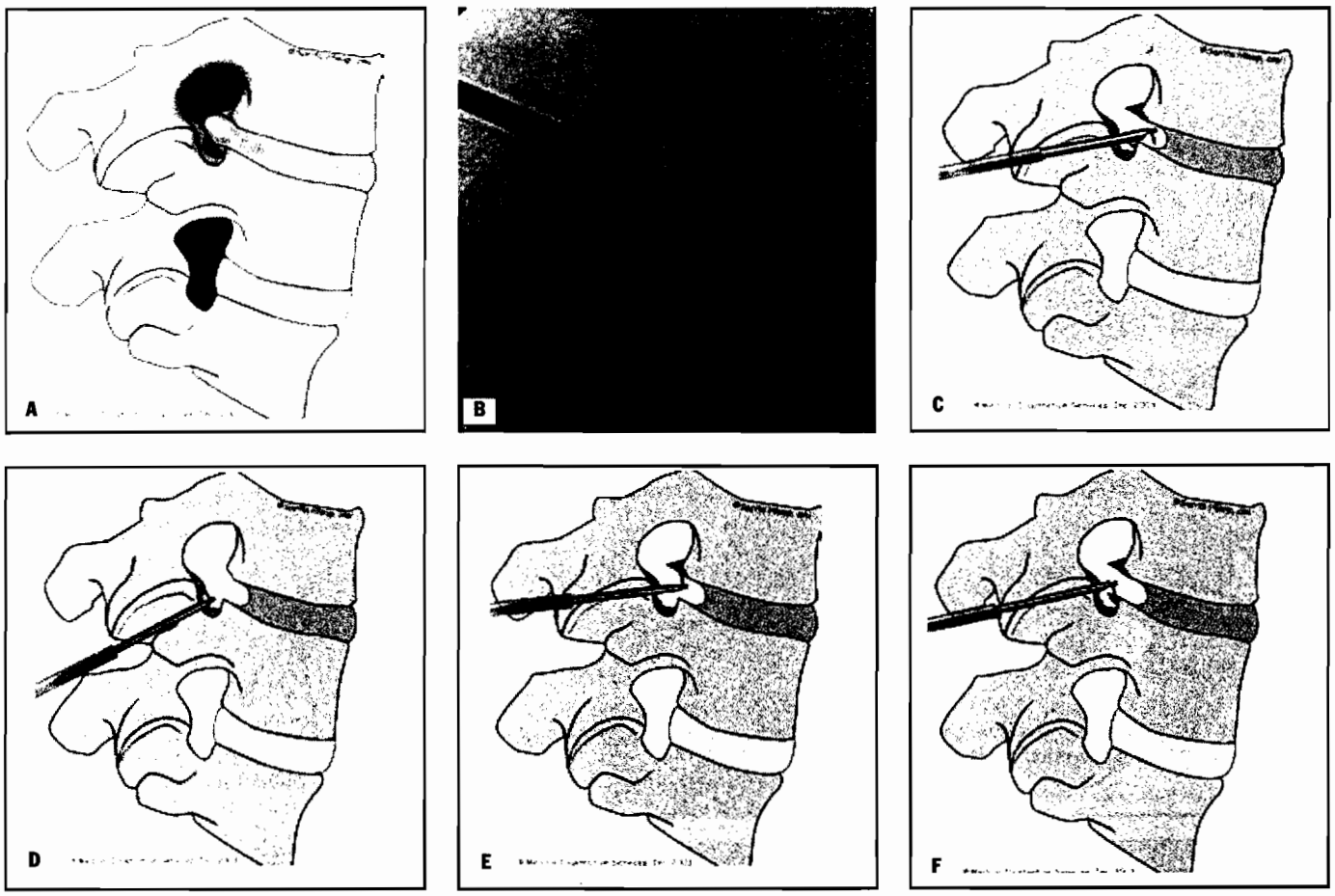


Figure 6. Fluoroscopic view and illustration of laser side-firing probe for lumbar laser foraminoplasty. (A) Illustration of lateral spinal stenosis secondary to disc protrusion, shoulder osteophytes, and facet hypertrophy. (B) Fluoroscopic view of side-firing laser probe at foramen for lumbar facet decompression. (C) Illustration of lumbar laser discectomy. (D) Illustration of lumbar laser foraminoplasty for facet hypertrophy. (E) Illustration of lumbar laser foraminoplasty for upper shoulder osteophyte. (F) Illustration of lumbar laser foraminoplasty for lower shoulder osteophyte.

OUTCOME

Since 1993, 2000 patients with a total of 3421 herniated lumbar discs (males: 1010, females: 990) underwent endoscopic lumbar discectomy. The average age of the patients with symptomatic lumbar single and multiple herniated intervertebral discs was 44.2 (24-92) years. Each failed at least 12 weeks of conservative care. Postoperative follow up was performed at 6 to 72 (average: 42) months. No postoperative mortalities occurred, and the morbidity rate was less than 1% in the 2000 patients. For single level, 94% of patients had good or excellent results, 6% had some residual symptoms although improved overall, and 3% of patients did not improve significantly. A newly devised, larger, and more aggressive decompressive discectomy instrument set (MEAD) safely and efficaciously allowed wider and more complete removal of large discs (single or multi level) or recurrent disc protrusions, scar tissue, and bony spurs that cause nerve root compression, while protecting the adjacent nerve root.

DISCUSSION

The TF-MEAD, with mechanical and laser application, using more aggressive instruments, allows wider and more complete removal of larger discs and decompressive foraminoplasty at bilateral and multiple levels in one sitting. It has proven to be safe and effective. To become competent and avoid complications, the TF-MEAD or surgeon must have a thorough knowledge of the surgical anatomy and procedures, specific surgical training with hands-on experience in a laboratory, and worked closely with an endoscopic surgeon expert at these procedures throughout the steep surgical learning curve.

ADVANTAGES

Decompression of the lateral recess and foramen is accomplished at a single sitting, and can be at multiple levels, bilaterally, or both, by a procedure having all the following advantages:

- ◆Same-day outpatient procedure.
- ◆Less traumatic, physically and psychologically.
- ◆Small incision and less scarring.
- ◆Zero mortality.
- ◆Minimal blood loss and little or no epidural bleeding.
- ◆No dissection of muscle, bone, ligaments, or manipulation of the dural sac or nerve roots.
- ◆Does not promote further instability of spinal segments or adjacent segment recurrent discs.
- ◆Commonly done under local anesthesia, and no general anesthesia necessary.
- ◆Multiple-level discectomy feasible and

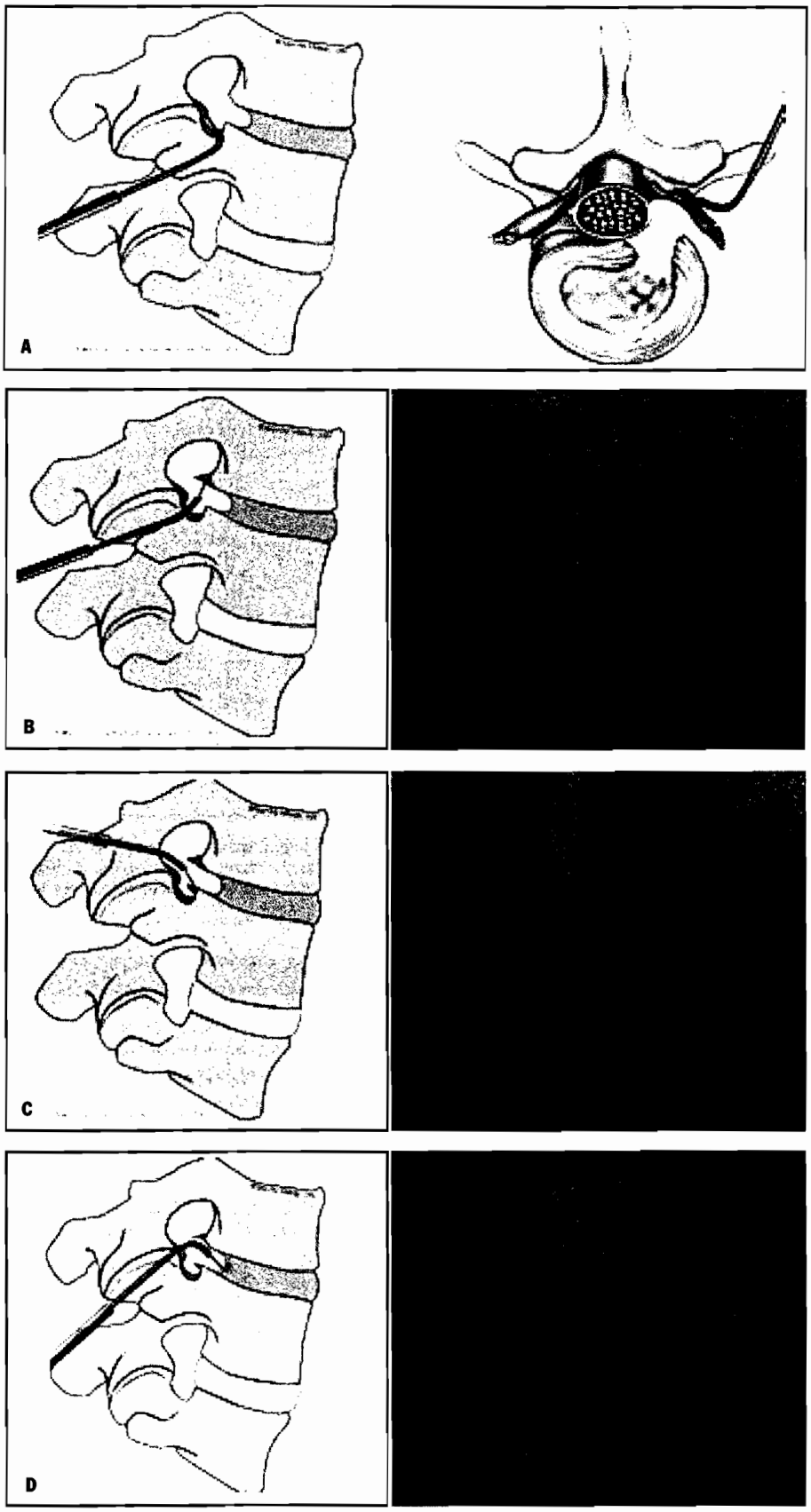


Figure 7. Fluoroscopic view and illustration of laser side-firing probe in action for lumbar laser foraminoplasty with steerable Spinoscope. (A) Illustrations of lumbar laser foraminoplasty with Spinoscope for facet hypertrophy (lateral & axial views). (B) Illustration and fluoroscopic lateral views of lumbar laser foraminoplasty with Spinoscope for upper shoulder osteophyte. (C) Illustration and fluoroscopic lateral views of lumbar laser foraminoplasty with Spinoscope for lower shoulder osteophyte. (D) Illustration and fluoroscopic lateral views of lumbar laser discectomy with Spinoscope.

well tolerated.[27]

- ◆Least challenging to medically high-risk patients and the obese.
- ◆Exercise programs can begin same day as surgery.
- ◆No significant incidence of infection.
- ◆Direct endoscopic visualization and confirmation of the adequacy of decompression.
- ◆Minimal use of analgesics postoperatively.
- ◆Earlier return to usual activities including work.
- ◆Costs less than conventional lumbar surgery.

COMPLICATIONS AND AVOIDANCE

A thorough knowledge of the endoscopic lumbar foraminoplasty and discectomy procedures and surgical anatomy of the lumbar spine and intervertebral foramen, careful selection of patients and preoperative surgical planning with appropriate diagnostic evaluations, and meticulous intraoperative techniques facilitate the TF-MEAD procedures and prevent potential complications. All potential complications of open lumbar disc surgery are possible, but are much less frequent[2,27,30] in endoscopic lumbar foraminoplasty.

- ◆Inadequate decompression of disc material: Minimized by using multiple modalities and instruments such as forceps, discectome, and laser application to both vaporize tissue and perform thermodiskoplasty (shrinking and hardening the disc with laser energy at a lower level).
- ◆Neural injury: Rare with MISS. Nerve root injury, although possible, can be avoided with the warning provided by continuous intraoperative neurophysiologic monitoring (EMG/NCV)[29] and direct endoscopic visualization. Operating strictly within the safe zone or triangle minimizes the root's exposure to injury.

Sympathetic nerve injury is extremely remote, as the procedure is largely intradiscal or in the foramen. Use of local anesthesia with a verbally responsive patient also provides a further warning system.

- ◆Ganglion (dorsal root) injury: One of the more common complications

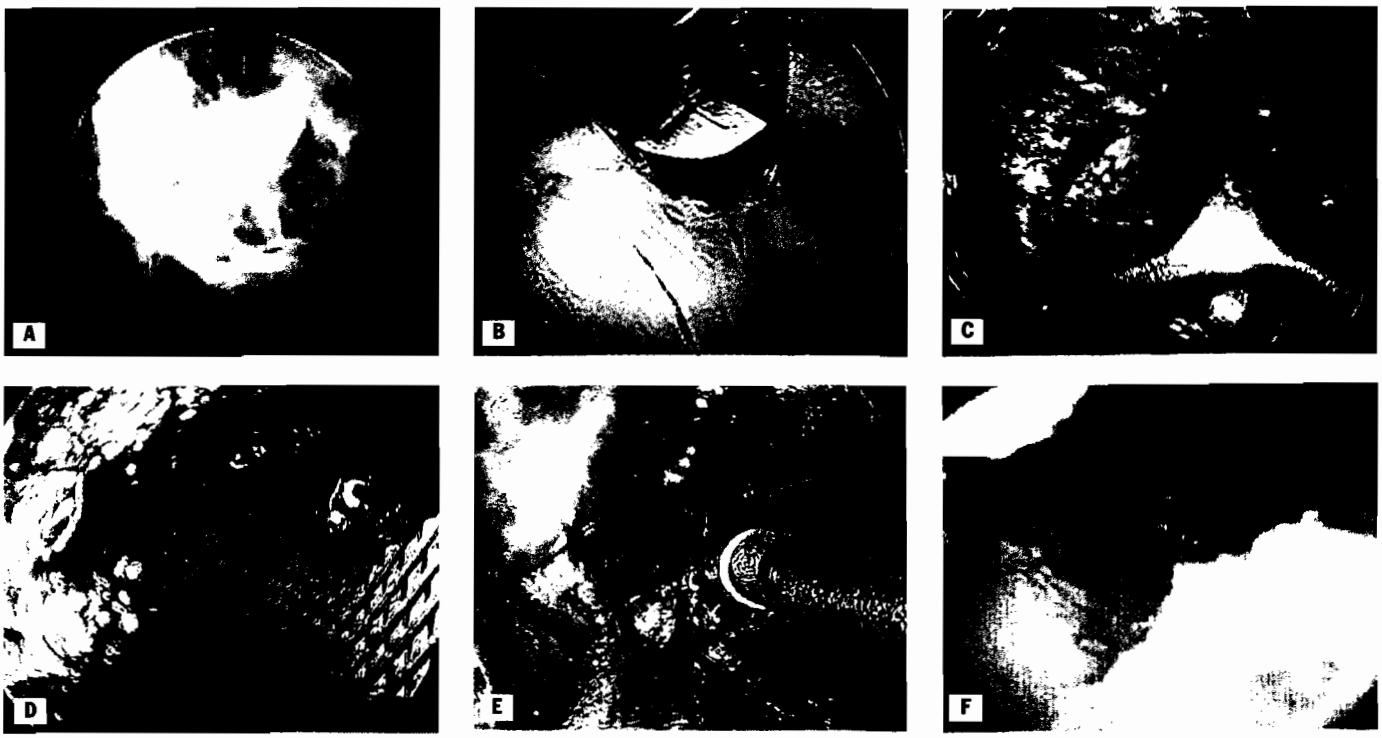


Figure 8. Endoscopic view of lumbar mechanical decompressive foraminoplasty and discectomy. (A) Disc removal with cutter forceps. (B) Disc decompression below the nerve. (C) Curette for osteophytic decompression. (D) Rasp for osteophytic decompression. (E) Bone punch/rongeur for foraminal decompression. (F) Disc and foramen appearance, post foraminoplasty and post discectomy.

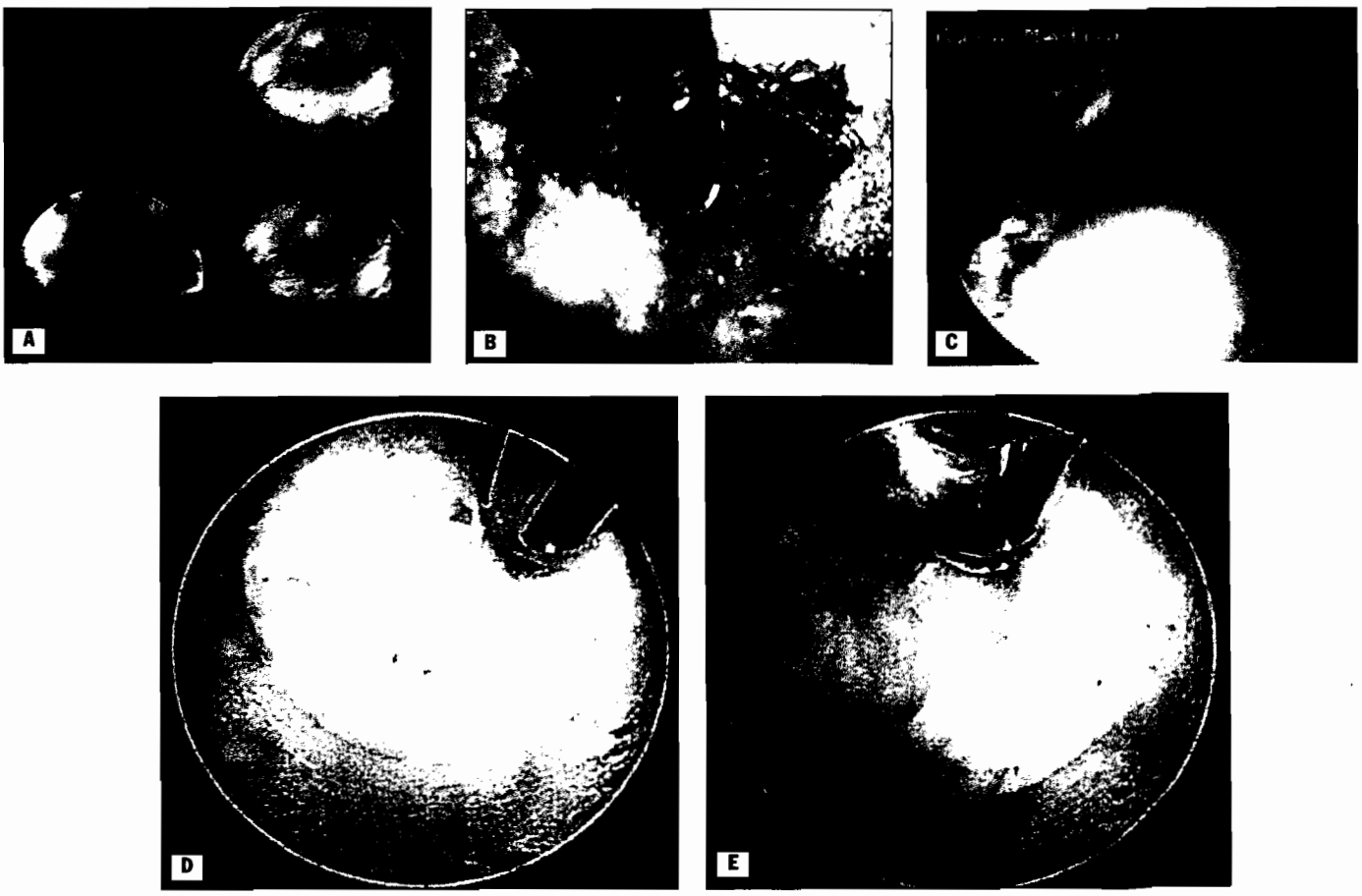


Figure 9. Endoscopic views of lumbar laser foraminoplasty, disc decompression, and laser Thermodiskoplasty. (A) After disc defect after decompression, and laser thermodiskoplasty with bare laser fiber. (B) Side fire laser probe in action for disc decompression and foraminoplasty. (C) Lumbar nerve root above the disc after disc decompression and foraminoplasty. (D) Disc before laser thermodiskoplasty. (E) Disc shrinkage after laser thermodiskoplasty.

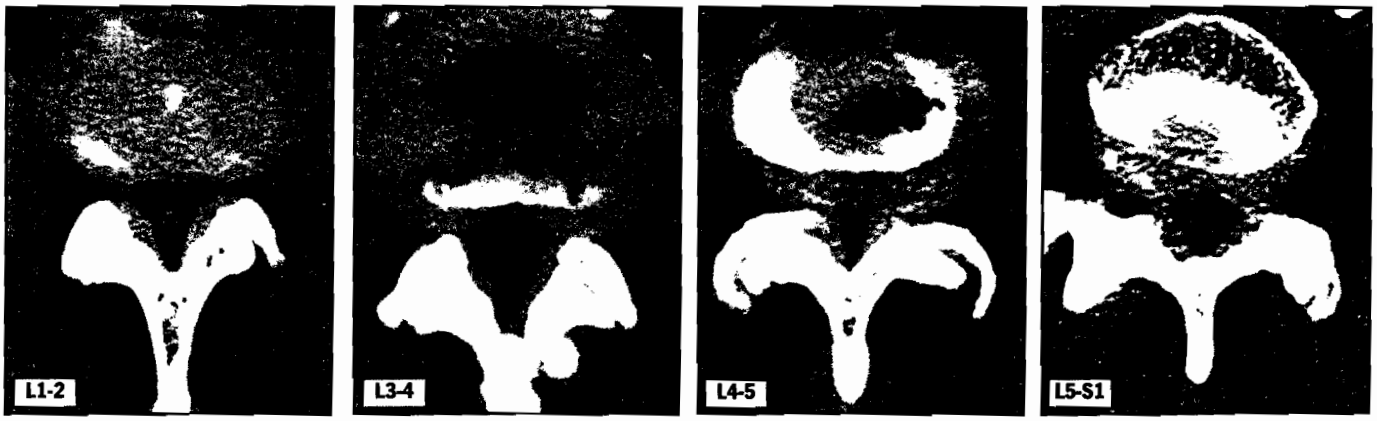


Figure 10. Axial CT images demonstrating severe bilateral lumbar foraminal stenosis secondary to posterior circumferential disc bulge/protrusion and facet osteophytic hypertrophy at L1-2, L3-4, L4-5, and L5-S1.

reported in posterolateral lumbar percutaneous approaches to the foramen is dysesthesia (the incidence of transient dysesthesia has been reported to be as high as 25% transient at one center but usually is less than 2%-3%, and permanent <1%)[30] in the leg on the operated side. Careful technique guided by close endoscopic and C-arm fluoroscopic monitoring and knowledge of the surgical anatomy of the lumbar nerve root, dorsal root ganglion, and foramen minimize this complication.

- ◆Operating on wrong level: A major complication of disc surgery at any level of the spine is operating at the wrong level. Proper use of digital C-arm fluoroscopy for correct anatomic localization avoids operating at the wrong disc level. Routine pain provocation test and discogram provides additional verification of the proper level.
- ◆Infection: Avoided by a careful sterile technique, the much smaller incisional area, absence of prolonged retraction of soft tissues, and by using prophylactic antibiotics I-V intraoperatively.
- ◆Discitis: Prophylactic antibiotics, continuous irrigation of the interspace throughout the procedure, and introduction of instruments through a cannula without contact with the skin tissues help minimize the incidence of infectious discitis.
- ◆Aseptic discitis can be prevented by aiming the laser beam in a "bowtie" fashion to avoid damaging the endplates (at 6 and 12 o'clock).
- ◆Hematoma (subcutaneous and deep): May occur with MISS (reported in the early literature), but is minimized by careful technique, not prescribing anticoagulants, aspirin, or NSAIDs within a week before surgery, doing a basic clotting screening preoperatively, application of gentle digital pressure or placing a full I-V bag over the operative site for the first 5 minutes after surgery, and application of an ice bag thereafter.
- ◆Vascular injuries: They are extremely rare when care is taken to remain within the disc space with stylettes and cannulae. The aorta, vena cava, femoral arteries, and veins are best avoided by accurate placement of all instruments. No vascular injury has been reported with lumbar MISS since the early experience with similar procedures.
- ◆Bowel and ureteral injuries: Ureteral injuries have not been reported with MISS. Bowel perforation was reported in the early experience, but was not reported in the recent multicenter study of more than 26,860 cases.[30]
- ◆Cerebrospinal fluid leak or dural injury: Dural injury has not occurred in any way other than as evidenced by spinal headache and presumed cerebrospinal fluid leakage. The incidence of only transient leakage in the multicenter study was less than 1%, and none required surgery to repair a dural tear.[30] Spinal headache has responded to simple blood patches.
- ◆Excessive sedation: Avoided by surface electroencephalogram (EEG) monitoring that provides more precise estimation of the depth of anesthesia, reduces the amount of anesthetics, and prevents excessive or insufficient sedation. Operations under local anesthesia with conscious sedation allow patient's responsiveness to be tested directly.
- ◆Soft-tissue injuries due to prolonged forceful retraction as occurs in many open disc operations are not an issue with TF-MEAD.

CONCLUSIONS

Evolving transforaminal endoscopic microdecompression for herniated lumbar discs and spinal stenosis has replaced open decompressive lumbar surgery for lateral spinal stenosis and disc herniation (Fig. 10) in this group of treated patients, and has proven to be safe, less traumatic, easier, and efficacious with significant economic savings. TF-MEAD is minimally invasive techniques, which decrease intraoperative and postoperative complications significantly by using endoscopic surgical techniques.

TF-MEAD combines more aggressive mechanical decompression and laser application to effectively treat spinal pathology at multiple levels and bilaterally. Many elderly patients (even octogenarians and beyond) who suffer symptoms caused by lateral spinal stenosis and disc problems can be treated successfully. The results of this operation can be an extremely gratifying experience for both the patient and the surgeon.

These procedures require a knowledgeable and competent surgeon with a thorough appreciation of the surgical anatomy. A minimally invasive spine surgeon must have specific surgical training with hands-on experience in the laboratory and, most importantly, must spend time working through the steep surgical learning curve with an endoscopic spinal surgeon expert present at this procedure. STI

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THE SPINE JOURNAL
A Multidisciplinary Journal of Spinal Disorders

Reprinted from
JANUARY/FEBRUARY 2002
VOLUME 2, NUMBER 1

Transforaminal endoscopic decompression for radiculopathy secondary to intracanal noncontained lumbar disc herniations: outcome and technique

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Received 27 February 2001; accepted 2 July 2001

Abstract

Background context: In 1973 Kambin and Gellman introduced the concept of percutaneous posterolateral extracanal approach in the management of radiculopathy secondary to lumbar disc herniation (LDH). This new surgical approach was recognized as potentially even less invasive compared with the microscope-assisted transcanal technique. However, the development of the posterolateral extracanal approach has witnessed a slow and complicated technique and equipment evolution.

Purpose: To report the surgical outcome, complications and technique of decompressing radiculopathy secondary to noncontained intracanal LDH using percutaneous extracanal access, the transforaminal endoscopic approach.

Study design/setting: Consecutive cases of LDHs from L3–S1 who had at least 1-year postoperative follow-up were included in this retrospective review.

Patient sample: Two hundred nineteen patients met inclusion criteria. There were 136 (62.1%) male patients, average age 41.5 years, and 83 (37.9%) female patients, average age 42.5 years. The age range was 17 to 71 years.

Methods: Two outcome measures were used. The first part was a surgeon-performed assessment. The second used a patient-based outcome questionnaire.

Outcome measures: The surgeon's retrospective assessment of excellent, good, fair and poor is a modified MacNab classification. The same terminology is used in the patient-based outcome questionnaire. Poor outcome resulting from technique failure is identified.

Results: Two hundred nineteen patients met the inclusion criteria. One hundred ninety-three patients also send back their completed questionnaire. The surgeon graded 88% percent of the 219 patients had a good or excellent result and the questionnaire subgroup 91.2%. The fair results were 5% of the 219 patients, 3.6% for the questionnaire patients. The poor results were 6.8% of the 219 patients and 5.2% for the questionnaire subgroup. The overall complication rate was 2.7% and missed fragment rate 0.9%.

Conclusions: Noncontained intracanal LDH fragments are accessible using the transforaminal endoscopic technique and equipment described. Retrospective outcome reviews of our clinical material showed results comparable to the reported findings in the literature for both the endoscopic and open transcanal decompression techniques.

Keywords: Transforaminal endoscopic discectomy; Posterolateral arthroscopic discectomy; Laser assisted discectomy; Foraminal annular window; Minimally invasive surgery for sciatica; Inclination of intervertebral disc; Chromatization of extruded disc fragment; Noncontained lumbar disc herniation; Foraminoplasty

FDA device/drug status: Not applicable.
Nothing of value received from a commercial entity related to this research.

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1529-9430/02/$ – see front matter
PII: S1529-9430(01)00153-X

Introduction

Noncontained intracanal lumbar disc herniation (LDH) can cause radiculopathy from chemical irritation and mechanical compression. With large herniations, symptoms of nerve root irritation may not spontaneously resolve because of persistent neural space compromise. The introduction of the operative microscope for spine surgery in 1967 by Yasargil [1] began the era of the minimally invasive surgical exposure for excision of LDH. The microscope-assisted discectomy quickly became the standard in miniaturization in surgical access. The transcanal microscope-assisted method, in its common practice, still requires general or regional anesthesia, retraction of the nerve root and the dural tube and subperiosteal stripping of muscle and ligamentous elements. In 1973 Kambin and Gellman [2] introduced the concept of percutaneous posterolateral extracanal approach in the treatment of radiculopathy secondary to LDH. The posterolateral endoscopic discectomy technique was recognized as potentially even less invasive compared with the more familiar microscope-assisted transcanal approach. The efficacy and versatility of posterolateral endoscopic access remains to be documented and confirmed by other investigators. Hermantin et al. [3] in 1999 reported satisfactory outcome of video-assisted arthroscopic lumbar microdiscectomy in 97% of patients as compared with the open discectomy's 93% in a prospective randomized study of 30 patients in each group. Specific technique-related difficult herniations were excluded from their patient selection pool. Their results showed that arthroscopic discectomy patients benefited from shorter time off from work, fewer days on pain medications, and quicker functional recovery.

In order to reduce technique-related exclusions inherent in earlier endoscopic reports [4–10], and to improve access to noncontained herniations, the transforaminal endoscopic method has evolved [5,11,12]. The outcome, complications and technique of transforaminal endoscopic excision of noncontained intracanal LDH in 219 consecutive patients are the subjects of this retrospective study.

Historical background

Kambin et al. [2–10] made numerous contributions to the percutaneous posterolateral discectomy procedure. His original effort in 1973 [2] was percutaneous nonvisualized limited nucleotomy using a Craig [13] cannula in conjunction with a standard posterior transcanal exploratory laminotomy. Stand-alone posterolateral percutaneous central nucleotomy, nonvisualized, was first reported by Hijikata et al. [14,15] in 1975, followed by Kambin and Gellman's report of nine cases in 1983 [2]. In 1983 Forst and Hausmann [16] reported the insertion of a modified arthroscope into the intervertebral disc space for direct visualization of intervertebral disc space. Schreiber et al. [17] used a biportal arthroscopic technique and injected vital dye, indigocarmine, to chromatize the abnormal nucleus pulposus and annulus. Kambin et al.'s [4] 1992 arthroscopic microdiscectomy paper reported a safe triangular working zone. This working zone was an extrapedicular space. Medialization of the arthroscope annulotomy site to the foraminal position was reported by Mathews [11,12] in 1994 and Kambin et al. [5] in 1996. To improve intracanal visualization and operative access, Yeung [18] medially extended and widened the foraminal annular window toward the opposite side of the spinal canal. Yeung [19] and Knight and Goswami [20] used Holmium-YAG laser to achieve bony foraminoplasty for decompression and enhanced access.

Methods

From August 1991 to February 2000, the senior author (ATY) performed uniportal and biportal transforaminal endoscopic excision of 219 consecutive intracanal noncontained lumbar disc herniations, L3 to S1. The average period from symptom onset to index surgery was 10.9 months. During the same period, 627 additional patients, not part of this study, underwent posterolateral lumbar endoscopic surgery for various other diagnoses.

The general patient inclusion criteria consists of symptomatic intracanal noncontained LDH at one level and no history of prior back surgery. On the correlating magnetic resonance imaging (MRI) studies, the leading edge of the herniated nucleus pulposus has breached all layers of the annulus fibrosus and extended 5 millimeters or more beyond the bony margins of the vertebra. The features of LDH noncontainment must first satisfy MRI evidence of full thickness annulus fibrosus disruption, and one of the following: 1) MRI evidence of transligamentous or extraligamentous location of nucleus pulposus fragment; 2) leakage of discographic contrast into the epidural space in a concordant anatomic location; 3) intraoperative findings of indigocarmine blue–stained nuclear fragment in the epidural space.

The surgical indications for the transforaminal endoscopic decompression technique for radiculopathy secondary to intracanal noncontained LDH are major motor weakness or unsatisfactory improvement under supervised conservative treatment for a minimal of 2 months duration. The elements of supervised conservative management consist of an activity abatement program, nontriplicate analgesics, nonsteriodal anti-inflammatory medication, selective nerve root block (2–3) or one course of Medrol Dospak. Unsatisfactory improvement was the result of persistence of motor weakness, intractable radicular pain and insufficient functional improvement. Patients who underwent endoscopic decompression must also meet the generally accepted objective indications for the open transcanal laminotomy and discectomy procedure.

This study does not exclude the "high iliac crest" or massive intracanal herniations. Personal injury and workers compensation cases were included in the study, if the patients met the inclusion criteria and the surgical indications.

Table 1
Location of the herniation

	Number of patients	Percentage
Intracanal		
Paramedian	167	76.3%
Central	52	23.7%
Total	219	100%
Transligamentous	94	43%
Disc level		
L5–S1	106	48.4%
L4–L5	104	47.5%
L3–L4	9	4.1%

No cauda equina syndrome was encountered in this consecutive series.

The apex of the lumbar disc herniations was within the medial borders of the pedicles. There were 167 (76.3%) paramedian and 52 (23.7%) central herniations (Table 1). Ninety-four patients (43%) were noted to have transligamentous herniations. The levels of herniation (Table 1) were as follows: L5–S1, 106 (48.4%); L4–L5, 104 (47.5%); L3–L4, 9 (4.1%). There were 136 (62.1%) male patients and 83 (37.9%) female patients. The average male patient's age was 41.5 years, and the average female patient's age was 42.5. The age range was 17 to 71 years.

Evaluation

The clinical outcome assessment employed two methods. Both were conducted a year or longer after the index operation. The first method was a surgeon-performed retrospective review of each patient's clinical record. The last office visit evaluation, after the first year, was used for outcome tabulation. The second method was an analysis of information gathered from a patient-based outcome questionnaire. The questionnaires were mailed between August 2000 and February 2001 and returned directly to the review surgeon (PMT) for analysis. The review surgeon did not take part in the index surgery nor meet the patients.

The senior surgeon (ATY) submitted the required clinical information according to a predetermined protocol. The items included preoperative history and physical examination, consultation, operating note, still image studies, intraoperative videotapes and laboratory reports. The postoperative data included the follow-up assessments, consultation and secondary operative note if reoperation had occurred. Follow-up examinations were carried out at postoperative day 2, week 2, 1 month, 2 months, 6 months, 12 months and every 12 months thereafter. Two hundred nineteen patients fulfilled the inclusion criteria with a minimum follow-up period of 1 year. The surgeon-performed retrospective outcome determination of excellent, good, fair and poor is a modified MacNab [21] guideline (Table 2).

The patient-based questionnaire provided the second method of outcome analysis determined by the patient's postoperative experience and satisfaction. The outcome is also categorized into excellent, good, fair and poor. For both methods of analysis, the fair and better grade also includes the requirement that these patients would select endoscopic surgery again in the future given the same surgical indications. The fair, good and excellent groups were satisfied with their endoscopic discectomy operation.

There are eight patient-based questions presented in Table 2, in horizontal layout format. The responses from the first four questions are given point values from zero to three. The first three questions are time dependent. These are in reference to time required from index operation 1) to resume customary occupation, 2) resume normal activities of daily living, including recreational sports, and 3) discon-

Table 2
Two methods of surgical outcome assessment: transforaminal endoscopic lumbar discectomy

	a	b	c	d
Patient-based outcome questionnaire, self-administered				
1. After my arthroscopic back surgery, I returned to my usual occupation in				
a) 1–2 months; b) 3–6 months; c) 7–12 months; d) > 12 months.	0	0	0	0
2. After my arthroscopic back surgery, I returned to my usual activities of daily living and recreational sports in				
a) 1–2 months; b) 3–6 months; c) 7–12 months; d) > 12 months.	0	0	0	0
3. After my arthroscopic back surgery, I ceased to take prescription drugs in				
a) 1–2 months; b) 3–6 months; c) 7–12 months; d) > 12 months.	0	0	0	0
4. My overall residue back/leg pain, if any				
a) none; b) mild, minimal functional adjustment; c) occasional, moderate work and ADL modification	0	0	0	
5. Since my arthroscopic back surgery, my back/leg pain is no better or worse than before the surgery.				0
6. I had re-operation at the arthroscopic back surgery level.				0
7. My arthroscopic back surgery was not satisfactory.				0
8. I will not select arthroscopic back surgery again if I encounter a similar sciatica problem in the future.				0
Surgeon assessment (modified MacNab)				
9. No pain and no functional restrictions	0			
10. Occasional back/leg pain, brief functional restrictions		0		
11. Improved overall function, permanent work and ADL modification			0	
12. No improvement of pain/function, or had index level re-operation				0

Items 1–4: a = excellent, b = good, c = fair, d = poor.
Items 5–8 and 12, column d = agree = technique failure, ADL = Activities of Daily Living.

tinue prescription analgesics and anti-inflammatory medications. For each of the above three questions, if the patient reached that milestone within 2 months, it was rated excellent; 3 to 6 months, good; 7 to 12 months, fair. Milestone reached after 12 months was rated poor, and no point is awarded. Questionnaire number four is patient's self-assessed level of residual back and leg pain. The cumulative point rating for excellent is 9 to 12 points; good, 5 to 8 points; fair, 3 to 4 points; and poor, 0 to 2 points.

The second four questions are yes or no type of questions. A response from any one of the four questions puts the patient's overall outcome in the mandatory poor category (technique failures). Eighty-eight percent of the questionnaires were returned. Twenty-six questionnaires were either unanswered or returned without a known forwarding address.

Transforaminal endoscopic technique in the excision of intracanal noncontained lumbar disc herniation

The authors' free-hand endoscope placement method uses biplane c-arm guidance. The c-arm images establish the following essential anatomic landmarks: anatomical disc center (Fig. 1, A), disc inclination line (Fig. 1, B) and the foraminal annular window (Fig. 1, A and C). The anatomical landmarks are topographically represented by line drawings. The percutaneous transforaminal approach to the intracanal and the intradiscal spaces must first enter the safe zone of the foraminal annular window (Fig. 1, A, and Fig. 3, A) from the skin window (Fig. 1, C). The skin window location is calculated from the target disc inclination line orientation, and the length of the inclination line from center of the disc to skin surface (Fig. 1, B). Use this method to locate the skin window, and then set the needle trajectory at 60 to 65 degrees from the parasagittal plane (Fig. 2). No surgeries have been aborted because of suboptimal endoscope placement.

The anesthetic method used is local lidocaine 1% infiltration. An anesthesiologist in attendance titrates short-acting opiate commensurate with the anticipated pain intensity generated by the endoscopic steps. The patient is placed prone on a radiolucent hyperkyphotic frame. The needle and the endoscope are inserted from the skin window directed toward the foraminal annular window, at 60 to 65 degrees trajectory, parallel to the target disc inclination, between contiguous end plates. Obtain biplane views when the needle tip has advanced just lateral to the pedicle for directional

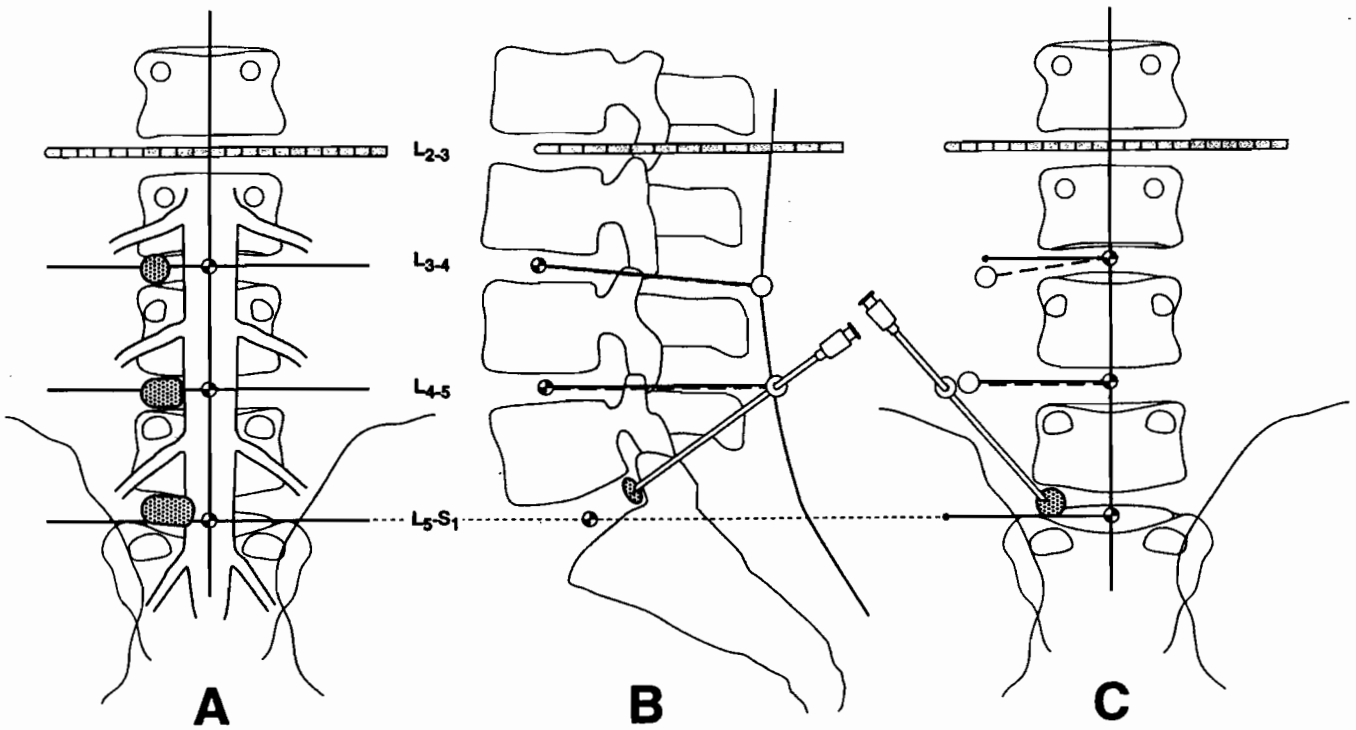

Fig. 1. Free-hand transforaminal endoscope placement method, using biplane c-arm images to localize essential endoscopic anatomic landmarks: foraminal annular window, skin window, disc center and disc inclination line. (A) In the posteroanterior projection, the intervertebral disc center is located at the intersect of the midline and transverse line (quadrant circles). The safe zone of the initial needle annular puncture is in the primary foraminal annular window, dotted circle, at the L3–4 level. Operative annular window medial extension and widening are shown at L4–5 and L5–S1 levels. (B) In the lateral projection, determine the intervertebral disc inclination line, which is drawn equidistant from the contiguous end plates. The needle position is superimposed on the L5–S1 inclination line. The perforated lines at other levels are the ideal trajectory for the needle path. The length of the solid line from the center of the disc to the skin surface is used in Fig. 1C as the lateral distance of the skin window (open circle) from the midline. (C) In the posteroanterior projection, the trajectory to the L5–S1 annular window is determined by the inclination of that disc. The L5–S1 inclination places the skin window (open circle) of that disc above the iliac crest. In the initial aiming of needle trajectory, the c-arm should be positioned in Ferguson view and view end plates in parallel. Note the L3–4 trajectory is pointed slightly cephalad because of a negative inclination of that disc.

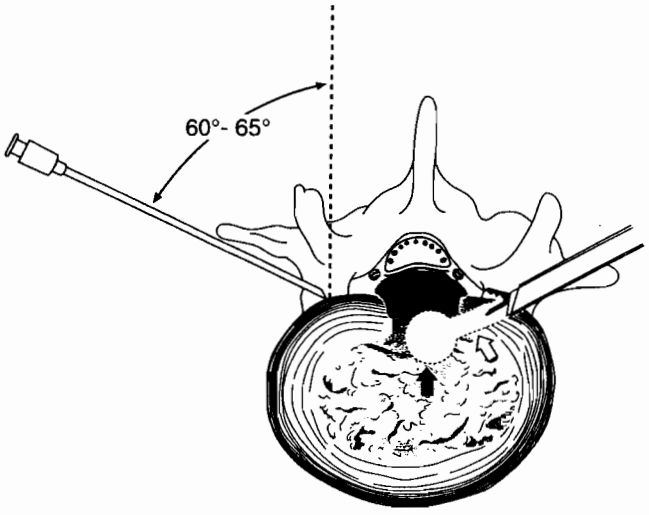

Fig. 2. The biportal transforaminal technique in the excision of a noncontained central lumbar disc herniation. The trajectory of the needle on the left is 60 to 65 degrees from the parasagittal plane. The right side of the illustration shows that the primary foraminal annular window had already been fenestrated. Proceed to excavate the working tunnel (open arrow) and the working cavity (solid arrow). The endoscope is straddled in the annular window. The straddle position shows the epidural space, annular wall and the intradiscal space in the same field of view. The method of medial extension of the annular window is shown here by biting opening the annular collar using the forceps under direction vision.

orientation, and redirect if necessary. The correct trajectory assures accessibility to the posterior annulus and the epidural space. Preparations for the intracanal nuclear material removal start with the excavation of an intradiscal working tunnel (Fig. 2, open arrow) and working cavity (Fig. 2, solid arrow). The annular window is medialized and widened to the vertebral edges using a side-firing Holmium-YAG laser (Fig. 3, B, right laser). The annular collar is opened using a forceps (Fig. 2, right). After an enlarged annulotomy has been carried out, remove all the blue-stained intracanal nuclear pulposus material from the epidural space. The entire herniation extraction is performed usually without any retraction or dorsal lifting of the traversing nerve root or the dural tube. The radius of intracanal exploration can be widened further by enlarging the intervertebral foraminal window (Fig. 3, B, left laser). This step is especially helpful in the presence of small intervertebral foramen resulting from narrowed disc space and incidental lateral recess stenosis. In cases of massive herniation resulting from annulus avulsion from one osseous-chondral vertebral corner attachment, the laser is used to sever the other vertebral corner attachment (Fig. 3, C).

During the operation or shortly afterward, most patients were able to discern the changes in their leg symptoms. The average surgery time is 45 minutes. Each patient spent 4 to 5 hours at the surgical facility for this procedure. Postoperative management included analgesics, and a progressive physical activity program. A corset was not used. The emphasis was on return to normal function within 2 to 3 months.

Results

Two hundred nineteen patients met the inclusion criteria and the minimal follow-up period of 1 year. The average follow-up period was 20 months, and the mean was 22 months. One hundred ninety-three patients of the primary group also sent back their completed questionnaires. The outcome tabulation by the two methods is listed in Table 3. The excellent or good results were 88.1% of the 219 patients, and 91.2% for the questionnaire subgroup. The fair results were 5% for the primary group and 3.6% for the questionnaire subgroup. The poor results were 6.8% for the primary group and 5.2% for the questionnaire subgroup.

Mandatory poor outcome, for what is considered technique failure, was given to patients who have expressed dissatisfaction about the results of their endoscopic discectomy, or any patient who underwent secondary back operation for whatever reason at the index level during the study period. Using the above criteria, five poor outcomes were the result of patient dissatisfaction. There were 10 poor outcomes related to secondary back operations. Six of the reoperations were the result of reherniation 6 to 12 months after the index operation. Two other reoperations were to the result of missed fragment in the presence of lateral recess stenosis. One patient needed wound debridement for deep infection and another to repair a dural tear. Three patients experienced postoperative ipsilateral extremity dysesthesia longer than 6 weeks. One patient developed deep vein thrombophlebitis. The patients who experienced dysesthesia and thrombophlebitis recovered from their complications, and their final outcome was not included in the mandatory poor group. There were no intraoperative vascular injuries, transfusions, motor deficit and perioperative deaths. The overall complication rate was 2.7%.

Discussion

The clinical outcome in 219 consecutive patients with radiculopathy secondary to intracanal noncontained lumbar disc herniation using the percutaneous transforaminal endoscopic technique was retrospectively reviewed. This series did not exclude large central herniations, herniations exceeding 50% of the anteroposterior canal length and the "high iliac crest." Ninety-four patients (43%) had transligamentous herniations. Considering that the entire series has higher grades of herniation and no technique-related exclusions for reasons of randomization uniformity, the satisfactory rate of 93.1% is comparable to the 97% satisfactory result of Hermantin et al.'s [3] arthroscopic microdiscectomy series.

Intracanal noncontained LDHs are accessible using the technique of transforaminal endoscopic 60 to 65 degree trajectory approach. Even in the presence of a large contiguous

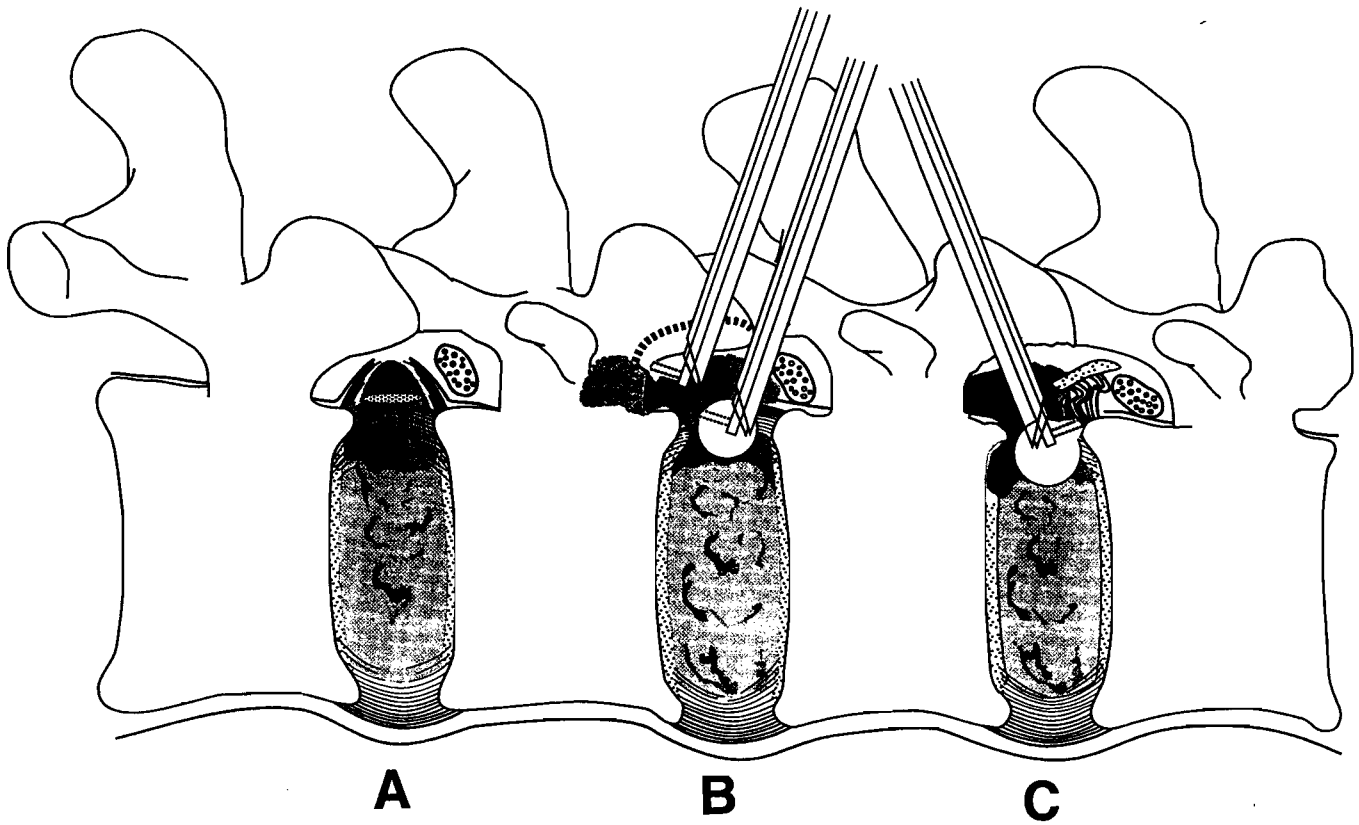

Fig. 3. Transforaminal endoscopic method in the excision of large noncontained disc fragments. (A) The safe approach zone is the foraminal annular window within the borders of the foramen, illustrated as a cylinder with dotted opening. The exiting nerve roots occupy the cephalad portion of the foramen. (B) After medially extending the approach primary annular window, a side-firing laser is used in the following manner to gain better exposure of the extruded fragment. The right laser is widening the annular window to the edge of the vertebral corner. The left laser is performing bony foraminoplasty, ablating the facet under surface and pedicle surface within the areas outlined. (C) In a massive disc extrusion of the hinged door variety, the annulus avulsion has occurred at one osseous-chondral corner attachment. Foraminoplasty is completed here to gain exposure. Use the laser to sever the tethered annular fragment at its other vertebral corner attachment before removing the entire disc extrusion.

transligamentous herniation, the approach requires no or little retraction on the nerve roots or the dural tube. Recentrum-located sequestrums without connectivity to the annulus or the disc space are rare. Free fragments located in the retrocentrum concavity cause less intense space-related symptoms as compared with a similar size fragment situated in the annular level. The intracanal accessible radius was improved with medialization and widening of the annular window. Foraminoplasty further enlarges the operative range. The laser-assisted bone ablation foraminoplasty effectively decompresses the dorsal component of the lateral recess stenosis when present. Kambin et al. [5] has described partial annulectomy to lower the floor component of the lateral recess and osteophyte excision using mechanical forceps.

Percutaneous posterolateral endoscopic discectomy has pushed back the frontiers of minimal invasiveness when compared with the gold standard of microscope-assisted transcanal discectomy. The endoscopic procedure is carried out strictly using local anesthesia and conscious sedation on an outpatient basis. The awake patient offers the best continuous interactive real time warning, should there be an inadvertent trauma to the nerve roots during the course of the procedure. Other benefits [3] of minimally invasive lumbar discectomy include less postoperative back pain, earlier functional recovery and no surgical destabilization. Comparing outcomes of discectomy by the endoscopic technique versus the traditional transcanal microscope-assisted method between different investigators is difficult at best [2,22–26]. Wide variations exist in patient selection criteria, surgical indications, length of follow-up, outcome measure, functional recovery and many other factors.

The major shortcoming of this study is that it is a retrospective outcome review of cases operated over a period of 9 years. There is no prospective randomization for the purpose of comparing outcome between treatment groups. Furthermore, the two outcome measure methods might be considered to be less than vigorous. The first is the surgeon-performed assessment. The second is a patient-based surgical outcome questionnaire, written by the authors. There are eight questions. The focus of the questionnaire is to uncover possible modification of the patients' clinical course and experience from the endoscopic spine surgery and to identify technique failure. Four questions were introduced to separate out cases that suffered obvious technique failure, from

Table 3
Outcome summaries of transforaminal endoscopic discectomy

	Physician assessment, modified MacNab	Patient-based outcome questionnaires
Number of patients	219	193
Excellent and good	193/88.1%	176/91.2%
Fair	11/5%	7/3.6%
Satisfactory (total of excellent, good and fair)	204/93.1%	183/94.8%
Poor	15/6.8%	10/5.2%

the successful or partially successful ones. There are no questions pertaining to psychometrics and generic health measures. The three questions query occupational status, activities of daily living and the level of residual pain. These questions profile patient's physical function and the level of residual pain symptoms. A similar category is present in the Medical Outcome Trust's SF-36 [27]. A fourth question defines patient's spine-related prescription drug usage, not a profile in SF-36 [27].

Twenty-six of 219 patients were questionnaire nonrespondents. More than half of the nonrespondents had their index endoscopic discectomy during the first half of the study period, and half of these questionnaires were returned without forwarding addresses. We have selected to list outcome by both the surgeon-performed assessment and the patient-based questionnaire method in Table 2. Deleting the questionnaire nonrespondents will introduce bias of its own, lower the complication rate and slightly reduce mandatory poor result. The nonrespondents from the earlier part of the study had one infection, one dural tear and three dysesthesias. There are reasons to believe that all known complications from a condition-specific surgical procedure should be reported in an outcome analysis [28]. No attempts have been made to calculate the statistical predictibilty of one method on the other. Epstein et al. [29] and Albert et al. [30] reported good predicting value of their surgeon-driven assessment and their patient-based SF-36 outcomes within the parameters of their studies.

The last 25 years witnessed a slow evolution in technique and equipment for the transforaminal endoscopic discectomy operation. Visualized intracanal fragment excision has only a short 9-year history.

The only known prospective randomized series [3] compared the posterolateral arthroscopic technique and the open transcanal method employed herniation size uniformity guideline that seems to bias in favor of the arthroscopic approach. Herniations then considered inaccessible using the arthroscopic technique, that is, large herniations and the "high iliac crest," were excluded from the selection pool. Moderate herniations were therefore preselected for the randomization process. The arthroscopic group therefore avoided some possible technique failures by not venturing into the technique-inaccessible situations.

Transforaminal endoscopic decompression of radiculopathy secondary to LDH is an uncommon procedure. The technique is precise, and the equipment usage is intense. There is a steep learning curve in the optimal operating endoscope placement and the proper usage of the extraction instruments. In the presence of "high iliac crest," large herniation and widened osteophytic L5–S1 facets, the authors use additional steps for extraction. The review surgeon is a fellowship-trained general spine surgeon. His transforaminal endoscopic discectomy learning experience included 1 month of hands-on instructions and many additional hours of reviewing intraoperative videotapes and reading operative notes. Potential transforaminal endoscope spine surgeons should commit similar or exceed these earning efforts outlined above before they attempt their first unsupervised endoscopic discectomy.

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September 5, 2007

Kerry N. Weems
Administrator Designee
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Rule [File Code: CMS-1392-P]

Dear Administrator Weems:

My name is Debbie Gafford and I am the CFO here at Menorah Medical Center. We are a provider of image-guided robotic stereotactic radiosurgery.

I thank you for the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) on CMS-1392-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates; Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates.

Medical linear accelerators (LINACs) were developed in the 1960's and allowed physicians to deliver isocentric radiation treatments to tumors over several weeks while sparing normal tissue. Advancements in computer and linear accelerator technology in the 1980's led to 3-dimensional conformal radiation (3D-CRT) and image-guided radiation therapy (IGRT) which combined computed tomography (CT) imaging with LINAC technology to identify the location of a lesion before and after a treatment session. In the 1990's, intensity modulated radiation therapy (IMRT) further customized the shape of the radiation field to better conform to the lesion.

In the 1950 and 1960's frame-based stereotactic radiosurgery (SRS) was developed to deliver radiation with a high degree of accuracy to the brain and skull base. This intracranial treatment relies on placement and adjustment of an external head frame and manual adjustment of the patient. The accuracy afforded by this technology allows delivery of large, single, ablative doses of radiation. Then, in the late 1990's, image-guided robotic stereotactic radiosurgery (r-SRS) proved significantly different from traditional radiosurgery in two ways: 1) no head or body frames are required, and 2) the flexibility of non-isocentric treatments allows for highly conformal treatments throughout the body together with a significant decrease in normal tissue radiation.

At present, the OPPS groups SRS into three ambulatory payment classifications (APCs). For CY 2008, however, CMS has proposed including two disparate technologies together with SRS in these APCs. We strongly disagree with this proposal, because we believe that it does not maintain the clinical and resource-related coherence that CMS usually maintains and that is exhibited by other APCs. The two technologies are ultrasound ablation of uterine fibroids with magnetic resonance guidance (MRgFUS) and magnetoencephalography (MEG). Neither of these technologies is similar to SRS and we urge CMS to move them to APCs more in accord with their clinical characteristics and resource uses.

Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS)

MRgFUS is not clinically similar to SRS. MRgFUS, a system by which high intensity focused ultrasound heats and destroys uterine fibroid tissue using sound waves. The mechanism of treatment for MRgFUS is most similar to that of Radiofrequency Ablation (RFA). Both MRgFUS and RFA ablate tissue by raising the

temperature high enough to lead to cell death. By contrast, stereotactic radiosurgery utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body (e.g., brain, lung, or spine).

Furthermore, the two technologies differ significantly in resource utilization. Unfortunately, claims information provides little reliable guidance on this point. MRgFUS is performed on very few Medicare patients and, therefore, very few claims are available. In CY 2005, for example, only two claims were submitted with a HCPCS code associated with MRgFUS.

The nature of the two treatments, however, provides a strong indication of resource differences. During MRgFUS, the treatment table containing the ultrasound transducer used to perform the procedure is rolled into conventional MRI equipment and the table is docked directly onto an existing MR scanner. The same MRI machine used to provide MRgFUS is also used to perform conventional MRI procedures and, therefore, does not represent an additional capital expense for the hospital. Moreover, no separate build out is needed to house the equipment, since an existing diagnostic suite is used to perform MRgFUS. In comparison, stereotactic radiosurgery requires the build out or retrofit of a lead-shielded vault, complete with special weighted mounting. Aside from the need for custom site construction, SRS systems are dedicated to the treatment of tumors and select disorders with high dose radiation; they are not used to perform other procedures that could mitigate resource requirements. Additionally, SRS treatment times are longer. Therefore, both operating and capital expenses are commensurately larger.

Accordingly, we urge reconsideration of the proposal to move MRgFUS into stereotactic radiosurgery APCs. We agree with the agency's assessment in the CY 2007 OPPS final rule that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

Table A. Overview of Clinical and Resource-Related Differences Between SRS and MRgFUS

Clinical/Resource Consideration	Stereotactic Radiosurgery	MRgFUS
Treatment Indication(s)	Treatment of benign and malignant tumors; other select disorders	Treatment of fibroids
Area(s) Treated	Anywhere in the body (e.g., brain, spine, lung, and liver)	Uterus
Patient Population	Men and women; Medicare and non-Medicare beneficiaries	Women under 65; Commercial insurance patients
Mechanism of Treatment	Precise, high-dose radiation	Focused ultrasound
Clinically Comparable Treatment(s)	Open surgery; radiation therapy	Radiofrequency ablation
Build-Out Requirements	Separate lead-shielded vault with special weighted mounting	No build-out required; diagnostic suite used
Additional Uses for Equipment	None; dedicated to radiosurgery	MRI equipment used for traditional imaging services
Claims Data Available (2005)	6,751 claims submitted[1]	2 claims submitted

1[1] Number reflects single claims (used in rate setting) submitted in 2005 with a SRS or r-SRS HCPCS code: G0173, G0251, G0339, or G0340.

Magnetoencephalography (MEG)

Public comments were not solicited regarding the reassignment of Magnetoencephalography (MEG) to Level I, II, and III Stereotactic Radiosurgery APCs. However, since the descriptor in the proposed rule for this series of payment classifications includes a change to incorporate MEG, and since this change is

inconsistent with the agency's policy of homogeneity within payment groups, we believe that public input is warranted.

MEG is also substantially dissimilar to SRS. It is an imaging technique used to measure magnetic fields produced by electrical activity in the brain. MEG, a diagnostic tool also known as Magnetic Source Imaging (MSI), is much like Magnetic Resonance Imaging (MRI). Both MEG and MRI produce internal images by recording magnetic signals and are used to provide information to aid in diagnosis. Their use is limited to obtaining information about the brain for diagnostic purposes. SRS, on the other hand is a therapeutic medical procedure that utilizes precisely targeted, large doses of radiation to destroy tumors and treat other select disorders anywhere in the body. SRS is clinically comparable to open surgery or, in some cases, other forms of radiation treatment.

Like MRgFUS, MEG is also performed on very few Medicare beneficiaries and, therefore, very few claims exist for comparative purposes. Between CY 2002 and 2005, no more than 23 claims were submitted for one of the three MEG CPT codes. The other two MEG CPT codes were reported on only eight claims combined during those years. Without sufficient claims data, a justification for resource similarity is difficult to make.

In light of the significant differences between a diagnostic tool such as MEG and a therapeutic medical procedure such as SRS, we request CMS reconsider its proposal to assign MEG to the stereotactic radiosurgery APCs. Moreover, we agree with the agency's previous comments indicating that resource and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

Table B. Overview of Clinical and Resource-Related Differences Between SRS and MEG

Clinical/Resource Consideration	Stereotactic Radiosurgery	MEG
Reason for Use	Therapeutic medical procedure	Diagnostic tool
Indications	Treatment of benign and malignant tumors; other select disorders	Measure electrical signals to aid in diagnosis
Area(s) Treated	Anywhere in the body (e.g., brain, spine, lung, and liver)	Brain
Mechanism of Treatment	Precise, high-dose radiation treats lesions and select disorders	Not a therapeutic treatment; used in conjunction with other diagnostic data in neurosurgical planning
Clinically Comparable Treatment(s)	Open surgery; radiation therapy	Not a therapeutic treatment
Claims Data Available (2005)	6,751 claims submitted[1]	31 claims submitted (CY 2002 – 2005)[2]

1[2] Number reflects single claims (used in rate setting) for claims submitted in 2005 with a SRS or r-SRS HCPCS code: G0173, G0251, G0339, or G0340.
1[3] Number reflects all claims submitted between CY 2002 and 2005. No breakdown specific to 2005 available.

SRS Treatment Delivery Services

We support CMS in its proposal to continue use of HCPCS codes G0173, G0251, G0339, and G0340. We agree with the assessment that these codes are more specific in their descriptors than available CPT codes, and that hospital claims data continue to reflect significantly different hospital resources which would lead to violations of the 2 times rule if the codes were cross-walked to CPT codes with less specific descriptors.

For CY 2004, CMS created two new Level II HCPCS codes, G0339 and G0340, in order to accurately distinguish image-guided robotic SRS systems from other forms of linear accelerator-based SRS systems and to account for the cost variation in delivering these services (CMS-1392-P). And, while there is now three years of hospital claims data, examination of the data reveals that there has been ongoing confusion among hospital providers resulting in cost and utilization data for SRS systems of all types being captured in the image-guided robotic SRS codes.

Since the agency's intent for CY 2008 is to continue using the G-codes for reporting LINAC-based SRS treatment delivery services under the OPPS, and to ensure appropriate payment to hospitals for the different facility resources associated with providing these complex services (CMS-1392-P), we respectfully suggest minor revisions be made to the coding descriptors for clarification purposes. We believe that coding confusion and thus inappropriate payments relate to the concept of 'image-guided robotics.' We believe that clarification of the descriptors is necessary in order to achieve the results intended by the agency's 2004 revisions, and we would be grateful for the opportunity to work together to accomplish these goals.

In summary, we appreciate the opportunity to comment and urge the agency to implement the following recommendations:

- MRgFUS is unlike SRS based on clinical coherence and resource utilization and, therefore, should not be moved into SRS APCs. As indicated in the CY 2007 OPPS final rule, retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable accurate payment rate setting and would maintain appropriate homogeneity of APCs.

- MEG, a diagnostic tool akin to MRI and used to measure magnetic fields produced by electrical activity in the brain, is in no way clinically similar to SRS, a radiation-based therapeutic medical procedure for the treatment of tumors and other disorders. Therefore, MEG should not be moved into APCs for SRS. As recommended by CMS in the August 2005 APC Panel Meeting, resources and clinical coherence suggest that this diagnostic test is most similar to services captured in APC 430, Level IV Nerve and Muscle Tests.

- Level II HCPCS codes, G0173, G0251, G0339, and G0340 should be retained. Further, we request clarification of the code descriptors in order for the agency to achieve its goals of distinguishing image-guided robotic stereotactic radiosurgery (r-SRS) systems from other LINAC systems, and accounting for the cost variation in delivering these complex services.

Sincerely,

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