

POSTERIOR VERTEBRECTOMY FOR HIGH THORACIC AND CERVICO-THORACIC VERTEBRAL TUMOURS

W. Sears

Department of Neurosurgery, Royal North Shore Hospital, Sydney, Australia

Introduction

The surgical management of patients with metastatic or primary malignant extradural tumours of the high thoracic (T4 and above) or cervico-thoracic spine is technically difficult. Various anterior approaches have been described, which may involve partial resection of the sternum or clavicle. Access is generally limited to lesions above T3 by the mediastinal great vessels and may be restricted by the patient's body habitus or kyphotic deformity associated with the tumour. Transaxillary approaches or high thoracotomy provide a restricted exposure of the anterior elements, may lead to subsequent scoliotic deformity and may require additional posterior decompressive and/or stabilisation surgery.

Roy-Camille first described the resection of tumours involving the thoracic vertebral bodies through a wide bilateral posterior approach in 1981. Modern spinal instrumentation has enabled the extension of this technique to tumours involving the high thoracic and cervico-thoracic region. When combined with thoracotomy to mobilise the anterior mediastinal structures, extensive en bloc resection and reconstruction may be achieved for primary malignant tumours of this region, involving multiple vertebrae.

This paper reviews the author's experience with this technique over the last seven years, to determine the efficacy and complications associated with the technique.

Methods

All patients underwent circumferential decompression of the thecal sac via a bilateral costotransversectomy approach. The vertebral bodies were reconstructed with bone cement or Titanium mesh cages/bone graft and stabilised with pedicle screws/rods (up to C6).

A retrospective review was done of all the patients who had undergone the surgery for malignant tumours involving between C7 and T4, over the last seven years.

Results

Nine patients underwent surgery for metastatic disease involving: C7/T1 – 1, T1 – 1, T2 – 2, T3/4 – 3. Two patients were lost to follow-up. Two patients (C7/T1, adeno and T1, thyroid) had undergone previous anterior surgery and presented with circumferential recurrent tumour.

Of the seven patients for whom follow-up data are available, two are still alive at 30 months (T1/2, breast) and 64 months (T2, prostate). Both remain ambulant, having presented unable to walk. Mean survival for the seven patients is/was 19.7 months (range 2-64). Six remain ambulant or remained ambulant up until the time of, or shortly prior to, their death.

No patient was made neurologically worse by the procedure. One patient who had previously undergone radiotherapy suffered a CSF leak and deep wound infection.

Two patients underwent surgery for primary chondrosarcoma. The first presented with recurrent circumferential tumour following previous left and right thoracotomies for tumour involving T2/3. The second presented with a large primary tumour involving T1/2/3. He underwent en bloc resection and reconstruction using Titanium mesh cages and pedicle screw instrumentation C6-T5, following anterior isolation of its blood supply. The first patient died of complications associated with a further thoracotomy, 18 months following the posterior procedure. The second remains alive and free of recurrent disease, 30 months post surgery.

Discussion

The posterior approach to excision of tumours lying anterior to the thoracic thecal sac is a useful tool for the spinal surgeon, especially in the high thoracic region. While patients with metastatic disease have a limited life expectancy, the neurological recovery, pain relief and maintenance of quality of life can be rewarding.

PERCUTANEOUS LASER DISC DECOMPRESSION FOR LUMBAR DISC PROLAPSE

P.J. Dohrmann

Victorian Neuroscience Centre at Epworth, Melbourne, Australia

Introduction

Percutaneous laser disc decompression is a minimally invasive surgical procedure with the potential to relieve symptoms due to nerve root compression by disc herniation. In this series, 42 adult patients with sciatica for a minimum of six months and in whom MRI had shown single-level lumbar disc herniation at L4-5 or L5-S1 were treated.

Methods

In all cases treatment was undertaken with a Holmium-YAG laser fibre under local anaesthesia. A posterolateral transforaminal approach with biplanar image intensification and endoscopic visualisation was used.

Results

Sixteen patients (38%) did not obtain relief and proceeded to open surgery within six months. A further 11 patients (26%) obtained no significant relief and elected conservative treatment. Fifteen patients (36%) expressed satisfaction with the outcome when independent telephone follow-up was undertaken at least 12 months after treatment. In one patient a broken guide wire was retrieved endoscopically. There was one case of nerve root trauma manifesting as persisting numbness and loss of the knee reflex.

Despite the overall results, there was a high level of patient acceptance of the procedure itself, and a low level of regret at having undergone percutaneous discectomy. Poor results were due in part to poor selection, particularly early in the series when patients with large herniations were included.

Discussion

In this series percutaneous lumbar disc decompression is a well-tolerated low-risk procedure with high levels of patient acceptability. However, it is a weak modality unsuited to large or paracentral herniations, and carries a high likelihood of failure with the need for subsequent conventional surgery.

Percutaneous laser discectomy was evaluated by the Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S)¹ and it was concluded that this treatment should be regarded as experimental, with largely unproven safety and efficacy.

References

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SUB-OCCIPITAL ANATOMY OBSERVED IN SAGITTAL SECTIONS.

J.R. Taylor

Australian Neuromuscular Research Institute, QE 2 Medical Centre, Nedlands WA 6009

During autopsy studies, 235 complete, formalin fixed, cervical columns were sectioned in 2.5 mm thick serial sagittal slices on a specially adapted band saw after freezing at -70°C . The sectioned spines included 146 spines from blunt trauma fatalities. Photographs were taken using a Leitz M3 dissecting microscope and camera. Anatomical features of functional and clinical importance which were observed will be described and illustrated.

Deep sub-occipital venous plexus: A venous plexus with multiple venous connections lies deep to the obliquus capitis inferior muscle (inferior obliques) behind the lateral atlanto-axial joint. This muscle has a strong fibrous lining on its deep surface which encloses a small compartment containing the venous plexus around the C2 dorsal root ganglion. The venous plexus has many connections including the vertebral veins, deep cervical veins and the intracranial venous sinuses. The veins are capable of very wide dilatation, as observed in patients with a history of chronic pain following injury. The thin walled veins may be injured in cervical extension injuries with the formation of a haematoma around the C2 dorsal root ganglion. The inferior oblique muscle itself may be injured by being nipped between the posterior arches of C1 and C2.

Sub-occipital nerves: It is said that C1 emerges between the vertebral artery and the posterior arch of the atlas to supply all the muscles of the suboccipital triangle but sections show branches of C2 innervating the inferior oblique muscle. The curved course of the greater occipital nerve around the lower margin of the inferior oblique may make the nerve and its ganglion vulnerable to stretch in patients with persistent muscle hypertonus associated with "occipital neuritis".

Upper cervical dura: Sections consistently show the posterior dura to be several times thicker than the anterior dura in the upper cervical region. Posterior connections to the posterior dura correspond to an insertion of rectus capitis posterior minor, a seemingly insignificant little muscle, which tensions the dura during extension movements to prevent it buckling towards the cord.

COMPLICATIONS OF CERVICAL MANIPULATION : THE AUSTRALIAN SCENE

C.R. Winer

Department Rehabilitation Medicine., Royal Prince Alfred Hospital, Sydney

Cerebrovascular Injury

The complication most commonly reported is cerebro-vascular injury. The first paper in Australia drawing attention to this risk was published in 1981 (Winer¹) a literature review, 56 cases, all overseas. Vertebro-basilar injury by manipulation usually affects the vertebral artery between C1 and C2.

The aims of this paper are to emphasise the under-reporting of manipulation complications, and to recommend a preventative step.

Case reports and literature reviews

Individual cases continued to be reported (overseas). Literature reviews were published in 1986 (Winer²), 1992 (Terrett³), 1993 (Powell⁴), 1999 (Haldeman⁵).

The 1999 paper, in Spine, by three chiropractors, found 115 such tragedies which had been reported. Yet this number is less than in the preceding two papers; this is partly explained by having surveyed only the English language articles, and partly because their survey covered papers only up to 1993.

In mid-1999, just prior to the publication of the paper by Haldeman, I had carried out a further Medline search so as to update the two publications by Terrett and by Powell. This search provides case histories of a further 30 CVAs. This brings the total of individual case histories reported to 156 cerebro-vascular tragedies. The majority (93) followed manipulation by chiropractors. The 156 CVAs include 20 deaths (17 by chiropractors). However, many cases go unreported.

Evidence of cases being unreported

An audience survey at a Stroke Conference in America yielded knowledge of 360 unreported cases of stroke, following neck manipulation⁶. A postal questionnaire to Neurologists in California yielded information on 55 cases previously unreported⁷. See the next paragraph for further unreported cases.

Australian experience

Five such CVAs occurring in Australia have been reported in medical publications⁸⁻¹². However, I have the details of a further 21 cases of cerebro-vascular injury which have occurred in Australia. These include six deaths (four following manipulation by chiropractors, and two by GPs).

Risk factors

Risk factors and screening tests will be discussed. However, the majority of these injuries occur in individuals with no pre-disposing factors and most commonly in the 30 to 45 years age group¹³.

Prevention

There is evidence from RCTs that manual mobilisation techniques are as effective as thrust manipulation¹²⁻¹⁴. My recommendation is that manipulators replace cervical thrust manipulation by gentle (osteopathic) mobilisation techniques.

References

1. Winer CER. Newsletter Aus Assoc Manip Med, Sept 1981
2. Winer CER. Aus Assoc Musculoskeletal Med Bulletin, 2.28-30, 1986
4. Powell FC et al. Neurosurgery, 33.73-79, 1993.
5. Haldeman S et al. Spine, 24, 8, 785-794, 1999.

A full list of references is available as hand-outs at the lecture.

RADIOFREQUENCY NEUROTOMY FOR THE TREATMENT OF THIRD OCCIPITAL HEADACHE

J. Govind, W. King and N. Bogduk

Newcastle Bone and Joint Institute, University of Newcastle, Newcastle, Australia

Introduction

Third occipital headache is pain in the head referred from a C2-3 zygapophysial joint and mediated by the third occipital nerve which innervates that joint. It is the basis for 27% of all headaches suffered by patients with whiplash¹. It is diagnosed by controlled diagnostic blocks of the third occipital nerve. However, this entity has lacked a proven treatment. Percutaneous radiofrequency neurotomy has been validated as a treatment for neck pain stemming from the cervical zygapophysial joints, but not for pain stemming from C2-3. Lord et al² attempted to treat third occipital headache by RF neurotomy but encountered a large failure rate. Accordingly they warned against attempting this form of treatment until the technical inadequacies of the procedure had been corrected.

Methods

Following analysis of Lord's previous experience, and having carefully considered variations in the anatomy of the third occipital nerve, and the size of lesions produced by RF electrodes, Lord's approach to this nerve was modified. The modifications involved ensuring that multiple lesions are made close together in order to accommodate variations in the course of the nerve; and holding the electrode in place throughout the procedure. The modified procedure was performed on 41 nerves in 38 patients diagnosed with third occipital headache. Successful outcome was defined, a priori, as complete relief of pain sustained beyond at least 90 days in the first instance.

Results

The modifications resulted in a reversal of Lord's experience, converting a 30% success rate into an 85% success rate. Only two patients failed to achieve relief for at least 90 days; three were lost to follow-up. In the other, the median duration of

relief obtained was 215 days (range: 90 - 500 days), with 16 patients still continuing with complete relief after 90 days. All 17 patients who previously used them ceased to take opioids. The success rate was not related to litigation. The principal side-effects were numbness, ataxia, and temporary dysaesthesia, none of which outweighed the welcome relief of pain appreciated by the patients.

Discussion

No other treatment for third occipital headache has been able to achieve complete relief pain in such a large proportion of patients. Provided that it is practised with meticulous attention to technical detail, percutaneous radiofrequency neurotomy is a valid treatment of headache arising from the C2-3 zygapophysial joints.

References

- 1 Lord S, Barnsley L, Wallis B, Bogduk N. Third occipital headache: a prevalence study. *J Neurol Neurosurg Psychiatr* 1994; 57:1187-1190.
- 2 Lord SM, Barnsley L, Bogduk N. Percutaneous radiofrequency neurotomy in the treatment of cervical zygapophysial joint pain: a caution. *Neurosurgery* 1995;36:732-739.

CERVICAL DENERVATION SURGERY FOR SPASMODIC TORTICOLLIS: AN INITIAL ASSESSMENT OF PATIENT SATISFACTION

T.R. Steel, M.J. Edger, I.T. Lorentz, P. Darveniza and M. Hayes
St Vincent's Hospital, Sydney

Background

Selective cervical denervation surgery for spasmodic torticollis was introduced into our institution in 1998. This procedure is reserved for patients with severe, disabling torticollis, which is non-responsive to medical therapy, including botulinum toxin injections.

Purpose

To assess patient perceptions and satisfaction following torticollis surgery.

Method

14 patients underwent cervical denervation between January 1998 and April 2000. Demographic details for each patient were recorded, and identically structured telephone interviews conducted, to assess degree of satisfaction, improvement, and any complications following surgery.

Results

No patients were lost to follow-up. Male:Female = 1:1. Mean age at surgery 51.5 years (range 29-70 years). Mean duration of torticollis prior to surgery 14.1 years (range 1 – 20 years). Mean interval between surgery and interview 16 months (range 6 – 33 months).

Ten patients (71%) felt that surgery had been worthwhile, with nine (64%) stating that, knowing the outcome, they would undergo the procedure again.

Thirteen patients (93%) had improvement in increased range of head movements and in resting head position. Mean improvement in head position 62% (range 10-95% improvement).

All patients who experienced pain pre-operatively had their pain reduced by the procedure.

Ten (71%) patients were able to reduce their torticollis medications, with six (43%) ceasing all their medications.

The mean duration between surgery and perceived maximum benefit was 4.5 months (range 1 – 10 months).

One patient experienced an unexpected neurological deficit (shoulder weakness). Four patients (29%) experienced unpleasant C2 distribution numbness. Three patients (21%) experienced new neck or wound pain.

Only one patient, who had an improvement for three months, experienced a return of all symptoms to, but no worse than, the pre-operative state, 24 months following surgery.

Conclusions

For a selected patient group, especially those with non-progressive torticollis, cervical denervation procedures can offer significant benefits in terms of head position, ability to conduct daily activities, reduction in pain, analgesic requirements and torticollis medication.

SURGICAL TREATMENT FOR CHORDOMA OF THE SPINE

F.J. Eismont

University of Miami School of Medicine, Department of Orthopaedics & Rehabilitation, Miami, Fl

Introduction

Chordomas are relatively uncommon tumours and make up only 2% of all malignant primary bone tumours. These tumours arise from notochordal tissue. These tumors typically affect patients in the fifth to seventh decades and occur most commonly in the sacrococcygeal region with a three to one male predominance.

Methods

Nineteen patients with the histologic diagnosis of chordoma were treated at the University of Miami by one surgeon between 1985 and 1999. Chart and x-ray reviews were carried out and data forms were created for each patient. A data table was compiled and basic statistical analysis as well as Kaplan-Meier survival curves with logrank analysis was done for independent treatment variables and their effect on overall survival time, recurrence, and time until recurrence.

Results

Nineteen patients, ten male and nine females were studied. The average age was 61 years with a range from 16 to 77 years of age. Thirteen tumours were located in the sacrum, three in the cervical spine, one in the thoracic spine, and two in the lumbar spine. All nineteen patients underwent surgical resection with nine undergoing en-bloc resection with wide margin, five undergoing marginal resection, and five undergoing intralesional resection. Twelve of the nineteen patients received adjuvant radiation therapy and two received chemotherapy in addition to the radiation therapy. Three patients had metastases at the time of diagnosis and surgery was done for pain control. 100% of the patients presented with pain at the time of diagnosis. 33% presented with clinical weakness, 39% presented with bowel, bladder or sexual dysfunction, and 54% presented with a palpable mass.

The average time until diagnosis was nineteen months with a range from three to 72 months. The average time of follow-up for survivors has been 77.6 months. For those who did not survive the time from surgery to death was 34.3 months.

There was a statistically significant increase in survival with adjuvant radiation therapy. Gender, margins, and palpable mass were not statistically significant variables in relation to overall survival.

At this time there are six patients with no recurrence, five patients are living with disease, and eight have died as a result of their tumour.

Discussion

In contrast to previous studies, radiation therapy has been found in our study to increase chances of survival following surgical resection of a spinal chordoma. Whenever possible, wide margin en-bloc resections should be performed.

THE BIOMECHANICAL BASIS OF INSTABILITY IN SPONDYLOLYTIC SPONDYLOLISTHESIS IS NOT EXCESS TRANSLATION, BUT RATHER, SEGMENTS OPERATING AROUND AN ABNORMAL POINT OF AXIAL COMPRESSION

G. Schneider, M. Percy and N. Bogduk
Specialist Manual Therapy Centre, Braidwood. NSW. Australia

Introduction

Two studies, conducted fifteen years apart, and using different techniques, measured the intervertebral translations in cases of spondylolytic spondylolisthesis. Neither study found evidence of hypermobility, in the form of increased forward shear, at the spondylolytic segments. In the light of these negative findings with respect to translation, it was decided to examine the quality of motion of spondylolytic segments, with the intention of defining a biomechanical basis for instability.

Method

Standing flexion/extension radiographs of fifteen patients were examined. Ten cases were a reassessment of the radiographs used in an original study. To this series five cases were added. Each of the fifteen cases had bilateral defects of the pars interarticularis at L5/S1, with grade one spondylolistheses in twelve cases, and grade two in three cases. The location of the instantaneous centre of rotation reflects the quality of motion of a segment, and is a mathematical function of the magnitude of translation of the moving vertebra, its rotation, and the location of the centre of reaction (CR). These parameters of motion were measured for the lower four lumbar segments of the flexion/extension radiographs, employing the same method of tracing and geometric constructions used to determine normative data.

Results

Excess anterior displacement (8 mm) was found in only one case at the spondylolytic segments. The singular most common abnormality of motion at the lytic segments was abnormally located centres of reaction. The CR was displaced posteriorly in six cases and anteriorly in one subject. With respect to all four parameters, abnormalities at the spondylolytic segments occurred in only 60% of the subjects. Abnormalities of motion occurred more commonly at levels above the listhesis. There was a higher incidence at the L3/4 segment (53%) than at the L4/5 segment (33%), with abnormalities at both levels in four of the fifteen subjects.

Discussion

The prevailing myth accounting for instability in these cases has been excess anterior translation. This abnormality was found in only one subject. Interestingly, there were two additional cases of abnormal retrolisthesis. In no other instance was there abnormal translation at the lytic segments. These findings are consistent with those of Percy, and later Axelsson. The unique features revealed, and hitherto unreported, were the abnormal and paradoxical motion that can occur at the lytic segments. The posterior displacement of the CR means that the lytic segment is operating around an abnormal point of axial compression, with weight focussed on the posterior anulus rather than the nucleus pulposus. More striking, however, were the inordinate and unexpected abnormalities at upper levels. It appears that the spondylolytic segments generate secondary biomechanical abnormalities at one, two, or even three segments cephalad. Biomechanical abnormalities are not confined to the lytic segment, and are most often not at that segment.

RADIOGRAPHIC ANALYSIS OF SPINAL MOVEMENT FOLLOWING THORACOLUMBAR FRACTURE FIXATION

N. Eames, D. Lisle and G. Askin

Princess Alexandra Hospital and Holy Spirit Hospital, Brisbane, Australia

Introduction

The management of thoracolumbar fractures with short segment internal fixation remains controversial. Many long term studies use the Cobb segmental index to evaluate radiological outcome. This measures kyphosis across the fracture segment spanning superior and inferior disc spaces. Little emphasis has been placed on the

amount of movement occurring around such fractures in the long term yet is often given as a reason for implant removal. Any movement which does return may affect measurement tools such as the Cobb index. This study analyses radiographically the movement occurring following such fractures.

Methods

25 patients who had suffered thoracolumbar fractures and had undergone internal fixation (Dick Fixator), posterolateral grafting and pedicle grafting were identified. These patients underwent (1) lateral x-rays in maximum voluntary flexion and extension, (2) AP x-rays in maximum voluntary side bending. The range of movement at each disc space was determined in addition to the Cobb segmental angle. Old x-rays from the time of injury and follow-up period were obtained and from these the bony reduction was analysed.

Results

Nine female, 16 males (mean age 38 years) were studied. 68% suffered A3 fractures. Only one patient had permanent neurological deficit. Minimum follow-up was two years from implant removal (mean six years, range two to 11 years). Mean time to implant removal was 13 months (range eight to 24 months). Analysis of movement showed in the sagittal plane a mean range of movement (ROM) of 5.6 and 6.2 degrees at the two discs proximal to the fracture segment. In the fracture segment, the ROM at the superior disc which was instrumented and underwent posterolateral fusion was significantly reduced (<0.001) to 0.4 degrees. At the unfused but previously instrumented inferior disc 4.1 degrees ROM occurred. A compensatory increase in movement of 9.4 degrees ($p=0.004$) was observed at the first distal uninstrumented disc. Similar results occurred in the coronal plane. The effect of this on the measured Cobb segmental angle depended upon whether this was measured with the patient flexed or extended, 76% of patients displaying a >4 degree difference with a mean of 5.1 degrees and a maximum of 15 degrees. Bony measurements showed in this series a mean improvement in vertebral height index from 39% depression pre-operatively to 18% post-operatively and 19% at long term review. A corresponding mean improvement in the vertebral wedge angle from 15 degrees pre-operatively to four degrees post-operatively and six degrees at long term review occurred.

Discussion

While movement was abolished at the superior disc of the fracture segment, significant movement occurred at the inferior disc. A compensatory increase in movement occurred distal to this. The effect of this on the Cobb segmental index was significant leading to large differences in derived values depending upon the position assumed by the patient. This has implications for the interpretation of long term results of thoracolumbar fracture management using such measures. This study also demonstrates that posterolateral grafting and pedicle grafting maintain sagittal correction after implant removal in A3 fractures.

ORIGIN OF MACROPHAGES IN A KAOLIN-INDUCED MODEL OF RAT SYRINGOMYELIA: A STUDY USING RADIATION BONE MARROW CHIMERAS

G. Lee¹, N. Jones¹, G. Mayrhofer², C. Brown¹, L. Cleland²

Department of Neurosurgery¹, Adelaide University, Royal Adelaide Hospital and Department of Rheumatology², Royal Adelaide Hospital

Introduction

Syringomyelia is an important condition in which a cystic cavity forms within the spinal cord. This leads to significant delayed neurological deterioration, which may be manifested as weakness, numbness or pain. The patho-physiology and mechanism of syrinx formation remains unclear. Human autopsy findings have demonstrated a prominent accumulation of macrophages in relation to the syrinx. Similar

observations have also been made in a previously established rat model of syringomyelia. Little is known about the origin and precise functions of these cells.

Methods

Syrinx formation was induced by intra-parenchymal injections of kaolin within the cervical spinal cords of 30 DA rat (RT7.1) radiation bone marrow chimeras reconstituted with bone marrow from RT7.2 congenic donors. The distribution of macrophages was evaluated at survival times of three days, one week and four weeks. Immunostaining of fresh frozen spinal cord tissue was performed using specific antibodies against rat macrophage ED1 antigen and RT7.2 allele of CD45. This allowed donor-derived haematogenous macrophages to be distinguished from native cells.

Results

Central canal dilatation was seen from one week. This was associated with extensive accumulation of ED1⁺ macrophages within the spinal cord parenchyma. A large influx of bone marrow derived (ED1⁺, RT7.2⁺) macrophages was observed. However, a considerable proportion of resident microglia (RT7.2⁻) also upregulated ED1. These activated microglia demonstrated distinct morphological features.

Conclusion

Large numbers of macrophages were recruited from the bone marrow in kaolin-induced rat syringomyelia. However, a significant number of resident microglia upregulated their ED1 activity and appear to provide a substantial source of macrophages.

STRESS ANALYSIS OF INTERBODY FUSION – A FINITE ELEMENT METHODOLOGY FOR MODELLING THE INTER-VERTEBRAL IMPLANT AND VERTEBRAL BODY

C.J. Adam¹, M.J. Pearcy¹, and P. McCombe²

¹Queensland University of Technology, Brisbane, Australia, ²Brisbane, Australia

Introduction

Interbody fusions using an inter-vertebral implant of the 'cage' design have become increasingly common in the field of spinal surgery in recent years. Spinal fusion implants must be capable of withstanding and transmitting the loads applied to them in vivo during post operative patient activity. However, subsidence failure of the vertebral end plate due to implant penetration is a common clinical finding.

Methods

This paper presents a finite element methodology to simulate the stresses generated by compressive loading of implants against an adjacent vertebral body. A benchmark three-dimensional finite element model is developed to simulate load transfer between a 'generic' implant geometry and an anatomically simplified vertebral body consisting of external cortical shell and cancellous interior. The finite element model is used to predict stress, strain, and deformation levels in each component at a given compressive load, and to determine the loads at which the onset of end plate subsidence failure is likely to occur. Numerical sensitivity analyses are performed to compare stress levels for a range of material properties with those of the benchmark model.

Results

Figure 1 shows predicted von Mises stress levels for the benchmark finite element simulation.

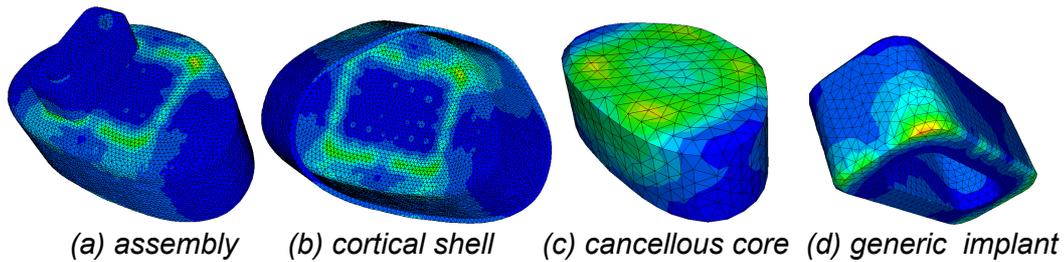


Figure 1: Predicted stress distributions for interbody fusion simulation

Discussion

Simulation results predict high end plate stresses beneath the anterior and posterior edges of the implant due to differing elastic bending stiffness (EI) between the implant and end plate structures. The elastic modulus of cancellous core material strongly affects load sharing between core and cortical shell, such that end plate stresses are 300% higher with degenerate (osteoporotic) core material. Maximum stress levels are also affected by interface friction coefficient and implant elastic modulus, but to a lesser extent.

EXCITOTOXIC MODEL OF POSTTRAUMATIC SYRINGOMYELIA IN THE RAT

N.R. Jones*, L.Yang*⁺, M.A. Stoodley[#], P.C. Blumbergs⁺, C.J. Brown*

*Department of Surgery (Neurosurgery), Adelaide University, Adelaide, Australia,

[#]Department of Neurosurgery, Prince of Wales Hospital, University of New South

Wales, Sydney, Australia, ⁺Neuropathology Laboratory, Institute of Medical and Veterinary Science, Adelaide, Australia

Introduction

In posttraumatic syringomyelia, primary injury and excitotoxic cell death occurring secondary to elevated levels of excitatory amino acids (EAAs) might initiate a pathologic process leading to the formation of spinal cavities. Subarachnoid block by arachnoiditis might promote enlargement of the cavities. An animal model was needed to elucidate the role of EAAs and spinal subarachnoid block in the genesis of posttraumatic syringomyelia. Our excitotoxic model produces intramedullary cavities, not dilatation of the central canal (canalicular syringomyelia) created by previous animal models. This model is suitable for studying posttraumatic syringomyelia (extracanalicular) to elucidate the role of excitatory amino acids (EAAs) and spinal subarachnoid block in the genesis of posttraumatic syringomyelia. We aimed to produce extracanalicular cysts in the rat spinal cord with quisqualic acid (QA), a potent agonist of multiple EAA receptors, and to compare the effects of excitotoxic injury only with that of excitotoxic injury and subarachnoid block with kaolin.

Methods

Three control rats received a unilateral injection of normal saline into the spinal cord and another five rats received an injection of kaolin into the spinal subarachnoid space. Twenty rats received a unilateral injection of QA into the spinal cord and an additional 13 rats received a unilateral injection of QA into the spinal cord following injection of kaolin into the subarachnoid space. Histological and immunocytochemical assessments were undertaken.

Results

In the control groups, no animal developed a parenchymal cyst. Spinal cord cyst formation was observed in 16/19 animals in the QA groups and no rat developed cysts greater than two segments in length of the spinal cord. Much larger cavities were seen in 9/11 animals in the group with QA plus kaolin and all these nine rats developed cysts greater than two segments.

Discussion

In posttraumatic syringomyelia, excitotoxic cell death occurring secondary to elevated levels of EAAs may contribute to the pathologic process leading to the formation of spinal cord cysts. Subarachnoid block by arachnoiditis is one of the pathogenic factors most likely to be responsible for causing enlargement of the cavity.

THE SAFETY, EFFICACY, AND COST-EFFECTIVENESS OF EVIDENCE-BASED GUIDELINES FOR THE MANAGEMENT OF ACUTE LOW-BACK PAIN IN PRIMARY CARE

B. McGuirk, W. King, J. Govind, J. Lowry and N. Bogduk.

Newcastle Bone and Joint Institute, University of Newcastle, Royal Newcastle Hospital, Newcastle, NSW, Australia

Introduction

Although several sets of guidelines have been promoted for the management of acute low back pain, there is no evidence that following guidelines results in better outcomes. To compare the effectiveness of evidence-based guidelines compared to usual care, a case-control study involving parallel, benchmarking, audits was undertaken.

Methods

Special clinics were established at which trained medical practitioners managed patients with acute low back pain according to evidence-based guidelines, and had their outcomes audited by independent research nurses. Meanwhile, and separately, the outcomes of patients managed by their own general practitioners were audited by research nurses using the same instruments of assessment.

Results

Under both conditions, patients showed remarkable degrees and rates of recovery, with low rates of recurrence. However, evidence-based medical care resulted in a significantly lesser cost of treatment; a significantly greater reduction in pain, sustained at six and 12 months; significantly fewer patients requiring continuing care at three, six, and 12 months; a significantly greater proportion of patients fully recovered at 12 months; and significantly greater proportions of patients rating their treatment as extremely helpful, and offering positive, unsolicited comments about their treatment.

Discussion

The immediate results of evidence-based care are marginally better than those of good usual care, but in the long-term, evidence-based care achieves clinically and statistically significant gains, with fewer patients requiring continuing care and remaining in pain. Consumers approve of evidence-based care.

EFFECTS OF INTERVERTEBRAL DISC INFECTION ON THE GROWING SPINE

R.M. Walters, S.H.E. Smith, M.J. Hutchinson, A.M. Dolan, B. Vernon-Roberts, R.D. Fraser and R.J. Moore

The Adelaide Centre for Spinal Research, Institute of Medical and Veterinary Science; Spinal Unit, Department of Orthopaedics and Trauma, Royal Adelaide Hospital; Department of Pathology, The University of Adelaide

Introduction

Discitis is thought to occur in children as a result of blood-borne infections that penetrate the highly vascular immature disc. The condition generally resolves without complication but little is known about the long-term effects on the growing spine. An ovine model was used to investigate the effects of discitis on spinal development.

Methods

Six-week-old lambs underwent lumbar discography at multiple spinal levels using either radiographic contrast inoculated with *Staphylococcus epidermidis* (inoculated group, n=21) or contrast only (control group, n=8). The animals were not given antibiotics, allowing the infection to run its natural course. Plain x-rays of the spines were taken at intervals up to 52 weeks for morphometric analysis of the vertebral bodies and discs. At each time point, one control and two inoculated animals were killed and their lumbar spines removed for histology.

Results

Discs from animals in the control group were radiologically and histologically normal at all time points, and as expected there was a steady increase in vertebral body and disc dimensions. The inoculated group was divided into two sub-groups – “inoculated with discitis” and “inoculated without discitis”. Sixteen of the forty-four inoculated discs showed histologic evidence of discitis. Disc height and disc area were significantly reduced from two weeks after inoculation and remained so throughout the study period. Thin discs were also seen in some of the inoculated animals which did not develop discitis.

Vertebral body dimensions and overall spine length were not significantly different compared to the control group at any time point. The area of vertebral body erosion associated with discitis peaked at four weeks but reduced over time until 52 weeks.

Discussion

Infection of ovine discs at a young age, whether or not it progresses to discitis, has an effect on intervertebral disc development. The failure of all inoculated discs to proceed to develop discitis suggests that the vascularisation of the immature disc allows an immune response to penetrate the disc and resolve the infection. This would explain why infections generally resolve without significant complications in children. Infection does not significantly disrupt the growth plate of the adjacent vertebra, allowing normal growth of the vertebral body.

TREATMENT OF DISCITIS FOLLOWING DISCECTOMY (OVINE MODEL)

D. Chapple, D. Goss, R. Moore, R. Walters and R. Fraser

The Adelaide Centre for Spinal Research, IMVS and The Spinal Unit, The Royal Adelaide Hospital, Adelaide, SA

Introduction

The purpose of the study was to determine the best mode of antibiotic administration for treatment of discitis following discectomy. Previous work¹ has shown that iv administration alone failed to prevent the course of established discitis. Recent work³ has shown improved efficacy (62.5%) at preventing discitis sequelae with intradiscal and iv antibiotic administration. This study investigated whether various antibiotic treatment regimens could have a therapeutic effect in cases of established discitis following discectomy. The timings for the start of treatment were taken from preliminary studies that indicated the earliest detectable MRI changes of discitis in the sheep model to be at seven days.

Methods

18 sheep were enrolled into three treatment arms. 1. iv antibiotics regimen. 2. Intradiscal antibiotics. 3. Intradiscal and intravenous antibiotics regimen. All sheep underwent a discectomy at three adjacent lumbar intervertebral discs and an intradiscal inoculation with a measured dose of *Staphylococcus epidermidis*. On the ninth day sheep requiring intradiscal treatment had a second operation to introduce under direct vision the antibiotic boli to the previously operated and inoculated discs. Follow-up radiographs were taken at six and 12 weeks. The lumbar spines were retrieved at 12 weeks for histological examination.

Results

50 of the 54 infected disc spaces progressed to show radiographic changes consistent with disc infection. 14/18 discs in iv antibiotics alone group; 18/18 discs in intradiscal antibiotics alone group; 18/18 in iv plus intradiscal antibiotics group.

Discussion

The results of this study suggest that antibiotic administration to treat discitis following discectomy at the earliest time of detection by MR imaging would result in failure to halt the progression of the infection. This would concur with earlier work from Fraser *et al*¹ in which iv antibiotics failed to stop progression of established discitis, but refutes previous findings³ of some efficacy of combined intradiscal and intravenous antibiotic treatment of discitis. Previous studies² have shown that prophylactic antibiotics prevented the progression of iatrogenic discitis and this study lends further support to their use in all procedures that violate the intervertebral disc as discitis once established has proven very difficult to treat.

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SPINAL INFECTION: A 20 YEAR EXPERIENCE

C. Charnley*, E. Athan*, M. McDonald*, D. Spelman†, O.D. Williamson‡

*Geelong Hospital, Geelong, Victoria, Australia, †Department of Infectious Diseases and Microbiology, Alfred Hospital, Prahran, Victoria, Australia, ‡Department of Epidemiology and Preventive Medicine, Alfred Hospital, Prahran, Victoria, Australia

Introduction

Spinal infections are uncommon, but if the diagnosis is delayed or missed, serious consequences may occur. Recently, there have been major advances in diagnosis and treatment of spinal infections.

Aim

To document the evolving clinical picture, diagnosis and treatment of spinal infection over 20 years.

Methods

Prospective and retrospective data were collected by infectious diseases services of a metropolitan referral centre and a provincial region. Clinical features, investigations, treatment and outcomes were analysed and comparisons made between two time periods, 1980-1992 and 1993-1999, and between the separate centres.

Results

115 patients presented, with an estimated incidence 1.7 cases/year/100,000. Over time, median age increased from 55 to 63.5 years and median time to diagnosis decreased from 28 to 21 days. The most common symptom was local back pain [112/115 (97%)] and common sign, local tenderness [88/115 (77%)]. Fever was present in 73/115 [63%]. Forty-one patients had neurological signs [36%] and 50 [43%] had epidural masses. MRI scan was the most accurate imaging method. All patients received antimicrobial therapy, 27 [23%] partly through an at-home programme, and 49 [43%] required surgery. At follow-up, 76% were considered cured without neurological deficit. Outcomes improved over time and differences between services reflected referral patterns.

Discussion

Over the last 20 years the management of spinal infection evolved through new diagnostic technologies, prolonged treatment with antimicrobials, appropriate surgical

intervention and a multidisciplinary approach. Heightened awareness of the condition is required to minimise the potentially serious consequences.

INFLAMMATORY CELLULAR RESPONSE AND CYTOKINES IL-1 β AND IL-6 IN EXPERIMENTAL SPINAL CORD INJURY

L. Yang*[#], C. Van Den Heuvel⁺, N.R. Jones*, J. Manavis[#], M. Ghabriel^φ and P.C. Blumbergs^{#+}

*Department of Neurosurgery, Royal Adelaide Hospital and Adelaide University,

[#]Neuropathology Laboratory, Institute of Medical and Veterinary Science,

⁺Department of Pathology, The University of Adelaide, ^φDepartment of Anatomy, The University of Adelaide, Adelaide, South Australia

Introduction

The temporal mRNA expression pattern of interleukin-1 β (IL-1 β) and interleukin-6 (IL-6) were correlated with the inflammatory cellular response (neutrophils, macrophages and microglia) as part of ongoing studies into the pharmacological modulation of the inflammatory response in experimental spinal cord trauma. It was hypothesised that the pro-inflammatory cytokines IL-1 β and IL-6 produced by intrinsic cells in the spinal cord act as messengers to coordinate the inflammatory cascade and the influx of neutrophils and monocytes to the site of damage and that the cytokine response should be greater in severe than in mild injury.

Method

Mild and severe spinal cord injury were produced by dropping a 10-g weight from 3.0 or 12.0 cm on to the exposed dura of rat spinal cord at the T12 vertebral level. An accelerometer attached to the weight yielded an oscilloscopic wave form from which force and impulse were calculated. Survival times following injury were one hour, three hours, six hours, one day and three days. The inflammatory cellular response was examined in tissue sections stained with H&E, a specific antibody ED1 against macrophages and a specific B₄-isolectin against microglia. Semi-quantitative reverse transcription polymerase chain reaction (RT-PCR) was used to quantitate the IL-1 β and IL-6 mRNA responses in mild and severe spinal cord injury.

Results

The nature and temporal development of the inflammatory cellular response was the same in both mild and severe spinal cord injury and differed only in degree, being greater in severe injury (statistically significant). Neutrophils were not detected at one and three hours after injury, dramatically increased at six hours postinjury primarily around blood vessels in the central gray matter and peaked at one day. Occasional ED-1 immunopositive macrophages were noted at six hours and then progressively increased predominantly in the central gray matter for the first three days postinjury. Lectin-positive microglia were mainly evident in the white matter and showed cellular hypertrophy and retraction of processes as signs of activation as early as one hour after contusion and increased dramatically at one day postinjury. Activated microglia frequently wrapped around axonal swellings and healthy neurons. RT-PCR showed an early and robust up-regulation of IL-1 β and IL-6 mRNAs in spinal cord after severe contusion injury, maximal at six hours postinjury with return to control levels by 24 hours postinjury, the changes being quantitatively less in mild injury.

Discussion

RT-PCR analyses together with histological observations suggest that intrinsic CNS cells, not peripheral inflammatory cells, are the main source for cytokine mRNAs because the peripheral inflammatory cells do not invade the injured spinal cord until six hours postinjury, a time when cytokine mRNA levels have peaked and started to decline. Furthermore, our comparative RT-PCR analyses, showing significantly increased expression of pro-inflammatory cytokine mRNAs in severe

injury in contrast to mild injury, support the hypothesis that cytokine up-regulation is an important factor in the generation of the severity of the inflammatory response and thus a suitable target for pharmacological intervention to attenuate this response.

SHOULD METHYLPREDNISOLONE BE USED FOR ACUTE SPINAL CORD INJURY : ARGUMENTS AGAINST ITS USE

M.D. Ryan

Royal North Shore Hospital and the University of Sydney

A debate will take place about the current status of the use methylprednisolone in acute spinal cord injuries. The material for the debate are the reports of the National Spinal Cord Injury Studies 1 and 2.

References

- 1 Bracken MB; Shepard MJ; Collins WF et al. (1990) 322:1405-1411. A randomised control trial of Methylprednisolone or Naloxone in the treatment of acute spinal cord injury.
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Dr Lali Sekhon, consultant neurosurgeon of the Royal North Shore Hospital, will put the case for the use of Methylprednisolone. Dr Michael Ryan, orthopaedic surgeon of the Royal North Shore Hospital, will put the case against its use.

METHYLPREDNISOLONE IN ACUTE SPINAL CORD INJURY: ARGUMENTS FOR ITS USE

L.H.S. Sekhon

Royal North Shore Hospital and the University of Sydney

Acute spinal cord injury is a devastating condition adversely affecting the quality of life of many people. Aside from prevention, our mainstay of therapy is minimisation of secondary insults and skilled nursing care. There is little class 1 or 2 evidence that any interventions ameliorate injuries once they occur, although non-pharmacological manoeuvres such as surgical decompression are being currently assessed. Methylprednisolone has been embraced as a possible limiter of secondary injury to the spinal cord, and to date little else has shown clinical efficacy. There is good experimental evidence that methylprednisolone reduces the extent of injury after spinal cord trauma. Any gains in function after cervical cord injury can lead to significant improvements in quality of life. Case selection can potentially reduce complications. Current studies do not definitively confirm the role of methylprednisolone as a standard of care in acute spinal cord injury. Until more promising therapies are developed, its judicious usage on a case by case basis is still, however, a viable treatment option.

THE NATURAL HISTORY OF INTERVERTEBRAL DISC DEGENERATION

M.J. Percy

School of Mechanical, Manufacturing and Medical Engineering, Queensland University of Technology, Brisbane, Australia

In the late 1960s and early 1970s Dr Harry Farfan proposed that tears in the annulus of the intervertebral disc were the result of torsional injury rather than from

compressive overload¹. Compression failed to produce damage to the intervertebral disc but torsional failure of the intervertebral joint produced circumferential separation of the peripheral laminae of the anulus. However, to produce this failure the intervertebral joints had to be rotated by at least 11° degrees (average 22.6°) and the normal range of rotation in life is only about 2°².

Studies have shown that prolapse of the disc posteriorly can be caused by compression applied to hyperflexed joints³. However, once again loading outside the range of normal activities was required to cause failure. Repeated trauma has also been hypothesised to cause progressive failure of the laminae of the anulus⁴.

When a normal disc with an hydrated nucleus is compressed the nucleus acts as an hydrostatic fluid and pushes out radially on the anulus. It has been suggested that as the nucleus dehydrates with age and degeneration it loses this hydrostatic character and no longer pushes out on the anulus. When the joint is compressed in this state the inner laminae of the anulus will tend to bulge inwards whilst the outer laminae still bulge outwards⁵, a finding confirmed in a recent study⁶. This might result in separation of the laminae.

A study of human intervertebral joints has provided evidence for the pattern of degeneration in the disc to begin with the appearance of circumferential tears followed by radial tears and anterior rim separation of the anulus from the vertebra⁷.

The evidence from the experimental studies can be interpreted to suggest how degeneration of the intervertebral disc begins and progresses. If circumferential tears are the first lesions to appear in the disc then the mechanism may be torsion. However, it is seductive to surmise that the natural progression of degeneration is for the nucleus to dehydrate causing the pattern of loading across the anulus to change. This might result in delamination of the anulus due to the differential bulging of the inner and outer laminae. This would cause further changes to the mechanics of the disc making the posterior anulus more vulnerable to injury from a combination of flexion and torsion and the anterior anulus more vulnerable to a combination of extension and torsion.

A pilot study has shown that enucleated discs subjected to 600,000 cycles of compressive loading exhibited evidence of separation of peripheral anular laminae (intact discs did not).

This is a model for the initiation and progression of disc degeneration and changes to the mechanics of the intervertebral joint.

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BONE MINERAL CONTENT IS INDEPENDENT OF THORACOLUMBAR VERTEBRAL END-PLATE THICKNESS: IMPLICATIONS FOR SURGERY

E. Trinajstic, R.I. Price, P. Woodland, B. Breidahl and K.P. Singer

Departments of: Orthopaedics, Medical Technology, QEII Medical Centre, Orthopaedics, & Radiology, Royal Perth Hospital, and University Department of Surgery, UWA. Perth

Introduction

The cartilage end-plate (E-P) is an important structure which interfaces between the vertebral body and intervertebral disc, balancing the demands of applied axial load while accommodating nutrient pathways through a highly porous membrane-like sheet. Estimating the mechanical competence of vertebral bone and the E-P is of critical importance in surgery involving the older patient. Our study sought to examine the relationship between vertebral bone density and morphology of thoracolumbar vertebral E-Ps from a range of non-pathologic post-mortem cases.

METHODS:

Following lateral vertebral body bone mineral content [BMC] assessment with dual energy x-ray absorptiometry [QDR 1000W, Hologic, USA], two para-sagittal plane bone slices were cut from all thoracolumbar vertebral bodies of 19 cases, aged 17 to 87 years [6 female and 13 male]. Using von Kossa stain, high resolution images of para-sagittal embedded and polished surfaces were digitised [Fig 1.]. Thickness measurements across the inferior and superior E-Ps were quantified by semi-automated image analysis [NIH-Image, Bethesda, USA] and averaged in relation to regions of the anulus and nucleus. Vertebral cancellous bone volume, from a defined region circumscribed within the cortical and E-P boundaries, was also calculated at each level.

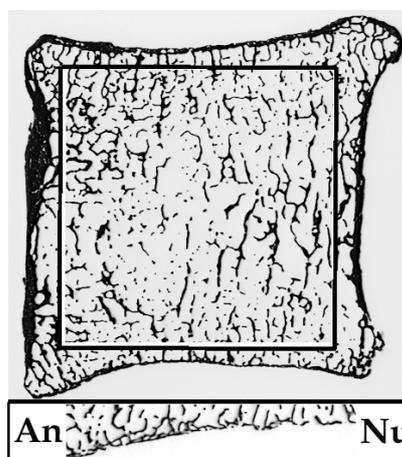


Fig 1. L1 vertebral section depicting region for measuring cancellous bone volume. Inset figure shows thicker anular [An] compared with nuclear [Nu] E-P.

Results

There was a progressive caudal [T1 to L5] and age-related reduction in BMC which correlated strongly with mean cancellous bone volume. Conversely association between BMC and end-plate thickness was weak. There were no significant gender differences for E-P thickness. The superior E-P was slightly thicker than the inferior, with significantly greater thickness in the anular region of the end-plate [Fig 1], whereas the region of the nucleus was more porous in nature [Fig 1]. Considerable variation was evident in end-plate morphology with some low thoracic and lumbar segments demonstrating a double end-plate trabeculation pattern.

Discussion

Vertebral BMC is an important guide to the surgeon in selecting anterior spinal constructs for use in older persons, however, BMC does not predict the calibre of the E-P and in cases of large Schmorl's nodes or osteophytosis may artifactually inflate BMC. With low BMC there is an acknowledged risk of subsidence of the E-P particularly with smaller centrally located spinal constructs. In predicting vertebral E-P competence quantitative CT would offer the dual advantage of demonstrating the pathoanatomy of the E-P and define the specific vertebral cancellous bone density of the involved segments.

A FINITE ELEMENT ANALYSIS OF THE L4/L5 INTERVERTEBRAL DISC UNDER COMPRESSIVE LOADING

P. Smallhorn, M.J. Pearcy, C. Adam, J.H. Evans and G. Pettet

Centre for Rehabilitation Science and Engineering and School of Mechanical, Manufacturing and Medical Engineering, Queensland University of Technology, Brisbane, Australia

Introduction

The presence of tears in the annulus fibrosus is commonly associated with disc degeneration and is thought to cause back pain. However, the mechanism of action of this process is not readily understood. The purpose of this study is to investigate the effect of annular tears on the biomechanics of the disc using a finite element (FE) model. A preliminary FE model of the L4/L5 disc was developed to analyse the response of the disc to compressive loading.

Method

The geometry for the transverse section of the annulus fibrosus and nucleus pulposus was based on specimen data obtained in a separate study carried out by Dr Nick Fazzalari at the Institute of Medical and Veterinary Science in Adelaide. The remaining dimensions were obtained from published literature.

The cartilaginous endplates were assumed to be an isotropic, linear elastic material. The ground substance in the annulus was represented as an incompressible, isotropic, hyperelastic material and the collagen fibres within the ground substance as an isotropic, linear elastic material. The nucleus was assumed to be a healthy, non-degenerate structure and was modelled as a hydrostatic fluid.

Discal loading was applied in a series of separate loading cases including loading to simulate the intrinsic intradiscal pressure, loading due to torso weight and additional static loads representing increasing portions of total body weight.

Results

A comparison of the stresses exhibited in the various loading cases indicated that irrespective of the level of compressive loading applied, the highest stresses were on the posterior margin of the superior surface. The highest stress contours were evident in the model with the peak compressive load applied. However, for the higher compressive loads the stress state in the models was such that the disc would no longer effectively function in a physiological setting.

The highest stress was present at the junction of the superior endplate and annulus. This location is to be expected, as this is the interface between two materials with different stiffness/compliance.

Discussion

It is postulated that the higher stress exhibited on the outer rim of the annulus is a result of the comparatively higher level of strain present on this edge. Regions of higher strain observed in the FE model coincide with regions where annular tears commonly occur in the disc.

Further development of the model, including more realistic material properties, will allow the effects of varying geometry and loading conditions to be investigated. Analysis of the response of the model will give a better indication of how and where annular tears develop.

LAMINOPLASTY-INDICATIONS AND TECHNIQUE

F.J. Eismont

University of Miami School of Medicine, Department of Orthopaedics & Rehabilitation, Miami, FL

Introduction

Laminoplasty was originally designed in order to expand the cervical spinal canal, maintain stability, and maintain motion. A goal of laminoplasty is to avoid repetitive

anterior decompressions and fusions resulting in long fusion. Expansive open door laminoplasty was first described by Hattori in 1972 and embellished by Dr. Hirobayashi in 1977. They found that this avoided the complications often seen with laminectomy.

Methods

From 1988 to 1991, twenty-seven patients underwent cervical laminoplasty and nineteen of those patients were available for follow-up. Their indications for surgery included multilevel stenosis (three or more), myelopathy, acceptable sagittal alignment, a stable spine, seven of the patients had multiple level radiculopathy.

Results

Twelve of the patients had excellent results, three of the patients had good results and four had fair results. None had poor results. This combined for a total of 78% good or excellent results. All patients with fair results had symptoms for more than eighteen months. All seven patients with radiculopathy improved, six of seven completely resolved their symptoms and one patient improved motor function but had persistent paresthesias.

Discussion

Neurologic recovery is dependent upon the duration of symptoms prior to surgery and the presence of objective signs of cord compression. Those with four or more long tract signs (positive Hoffman signs, positive Babinski signs, clonus, L'hermitte sign, hyperactive reflexes in the arms, and hyperactive reflexes in the legs) had a greater degree of improvement. Laminoplasty safely decompresses multiple level stenosis. This results in improved neurologic function in 78% of patients with myelopathy. This also successfully treats radiculopathy. 145 patients have undergone laminoplasty at this time and these same results have been found. The technique for this procedure and follow-up examples will be shown.

PROSPECTIVE EVALUATION OF THE SB CHARITÉ III DISC PROSTHESIS

S.L. Blumenthal¹, P.C. McAfee², S.H. Hochschuler¹, R.D. Guyer¹, I. Fedder², D.D. Ohnmeiss³

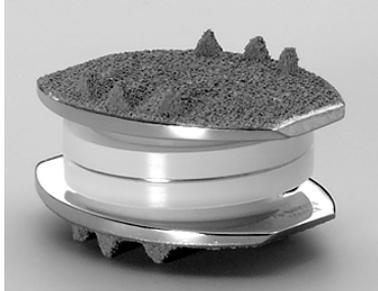
¹Texas Back Institute, Plano, Texas USA; ²Orthopaedic Associates, Towson, Maryland, USA; ³Texas Health Research Institute, Plano, Texas

Introduction

For many years there has been a great deal of interest in artificial lumbar discs, resulting in many prosthetic designs. Among them, the SB Charité III (Link) has been used the most, having been implanted in Europe for more than 10 years. The few published articles on this device, using retrospective outcome assessments, reported good results in 63% to 79% of patients^{1,2,3}. The purpose of this prospective study was to evaluate surgical outcome following implantation of an artificial disc.

Methods

The SB Charité III device has two cobalt chromium plates with a polyethylene core between them (Figures 1A and B). Motion occurs through articulation between the concave/convex surfaces of the plates and core. The disc prosthesis is implanted using the same approach as used for anterior lumbar interbody fusion procedures. It comes in multiple sizes to accommodate



1A



1B

Figure 1A. Each metal plate has 6 spikes that anchor the device into the vertebral body. **1B.** The convex inferior and superior surfaces of the core are surrounded by a rim that fits around a ridge in the plate to prevent displacement.

The disc has been implanted in 42 patients at two centers. There were 23 males and 19 females (mean age 41.2 years, range 25 to 55 years). The indications included single-level symptomatic disc degeneration, failure of at least six months of non-operative treatment, and no previous surgery at the operated segment. Outcome measures included neurological examination, radiographic assessment, Oswestry Low Back Pain Disability Questionnaire, visual analog scale, SF-36, and work status.

Results

Overall, patients demonstrated improvement in the self-reported outcome measures. More improvement was seen early in the Oswestry and visual analog scale scores than on the SF-36. Radiographic assessment revealed no cases of device displacement or migration. Complications were comparable to those reported for threaded fusion cages and included ileus, neurological worsening (resolved), excessive bleeding, and bowel perforation. There have been no cases of device failure.

Discussion

The results of this prospective study, using patient self-report questionnaires, demonstrated good clinical outcome. The disc prosthesis can be implanted safely, with complications similar to those encountered with anterior lumbar interbody fusion. The artificial disc appears to have promise as an addition to the treatment armamentarium for back pain. As with any surgical procedure, long-term prospective follow-up is needed.

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A PROSPECTIVE STUDY OF A TITANIUM/POLYOLEFIN ARTIFICIAL LUMBAR DISC

B.J. Freeman, R.D. Fraser, E.R. Ross, G.L. Lowery and M.J. Dolan
St Andrew's Hospital, Adelaide, South Australia

Introduction

The purpose of this study was to evaluate the design of a titanium/polyolefin artificial disc, refine the surgical technique, assess safety and measure outcome to determine if an RCT is justified.

Methods

All subjects entered this pilot study with single level disc disruption at L4/L5 or L5/S1 and had disabling LBP of at least 12 months duration. The diagnosis was confirmed by discography. An independent assessment included physical examination, visual analogue scales (VAS) for pain, Low Back Outcome Score (LBOS), Oswestry Disability Index (ODI), SF-36, lateral flexion/extension radiographs and MRI. The assessment was carried out preoperatively and at six and 12 weeks, six months and one and two years. Surgery was performed by an anterior retroperitoneal approach.

Results

Eleven cases (seven males; average age 41 years) have been operated on since April 1998. Surgery was carried out at L5/S1 in 10 cases. Three patients have been followed for two years and eight for 12 months. The OR time averaged 135 minutes with 140 mls average blood loss. There were no operative complications and the average length of stay was 6.3 days. At one year there was a 39% average

improvement in VAS, 12 point average improvement in ODI, 14 point average improvement in LBOS and improvement in five of the eight SF36 sub-scales. Complications were limited to early partial displacement of the implant in one case and late hetero-topic calcification in another.

In 10 patients satisfactory movement of the vertebral motion segment was shown by cine-fluoroscopy and this was found to be superior in demonstrating this than were standing lateral flexion/extension radiographs.

Discussion

Although a satisfactory clinical outcome was obtained, technical difficulties with insertion, the case of partial implant displacement and radiological evidence of sub-optimal endplate contact have led to refinement of the titanium endplates. The refined prosthesis is undergoing further evaluation before commencement of an RCT.

BIOMECHANICAL CHARACTERISATION OF A NEW LUMBAR DISC PROSTHESIS

*H. Serhan, *R. Ross, *G. Lowery and *R. Fraser

*Raynham, MA, USA, *Department of Orthopaedics & Trauma, The University of Adelaide, Adelaide, South Australia

Introduction

The artificial disc consists of proprietary polyolefin rubber core bonded between two titanium endplates. It has been developed for the treatment of symptomatic disc degeneration with the aim of providing segmental stability and motion following wide disc space clearance. It was designed to have similar properties to a normal adult human intervertebral disc when working in conjunction with the retained anulo-vertebral tissues and the supporting musculoligamentous system.

Methods

Over 120 discs were used to biomechanically characterise the Device. Range of motion tests were designed and performed to measure the axial compression, torsional, and shear stiffness of the artificial disc and to compare this with the known values for the human lumbar disc. Pullout test was performed to evaluate the immediate and short-term stability of the inserted device by assessing the mechanical resistance to pullout or expulsion. To assess the ability of the implant to withstand average daily living loads throughout its predicted life, compression and compressive shear fatigue testing were performed.

Results

The following table summarises the in-vitro testing to characterise the biomechanical properties of the device

Performance Characterisation	Test	Results
Static Mechanical Properties	Compression >47,000N Compressive Shear >14 mm Torsion >60 degrees	>7 times vertebral body strength >4 times <i>in-vivo</i> 2.8 mm A/P Displ. 20 times <i>in vivo</i> 3 deg rot. Displ.
Fatigue/Durability	>3,400N Compression and >5 mm Compressive Shear translation	10 million cycle run-out exceeds average <i>in-vivo</i> daily living loads and displacements
Range of Motion (Stiffness)	Compression, Torsion and Shear	replicates many of the physiologic characteristics of the <i>in-vivo</i> FSU
Expulsion/Pullout	Disc Pullout Strength >750 N	Higher pullout than femoral allograft ALIF ring

Discussion

The device was found to replicate many of the physiologic characteristics of the in-vivo FSU. The quasi-static testing showed the device to have higher strength values than the highest *in-vivo* loads and displacements. Fatigue testing showed the smallest device endurance limit of 3,500N at ten million cycles. The results demonstrate that the failure modes of the device contain sufficient safety margins to support the use of the device in a prospective clinical study.

EARLY CLINICAL EXPERIENCE WITH THE BRYAN CERVICAL DISC PROSTHESIS

V. Bryan

Surgical Dynamics, New York, USA

Major advances in arthroplasty for the treatment of joint disease have occurred over the past forty years as evidenced by the success of total hip and knee replacement procedures. However, the standard of care for the treatment of degenerative disc disease in the spine remains arthrodesis. Numerous reports in the literature suggest that symptomatic degeneration of intervertebral discs adjacent to fusions leads to cumulative average reoperation rates of between 2.5% and 3% per year. A retrospective radiographic study¹ of approximately 200 patients with a minimum five-year follow up documented degenerative changes in up to 90% of patients at levels adjacent to single-level fusions.

In order to address these issues, a patented intervertebral disc prosthesis system (Bryan™ Cervical Disc prosthesis and supporting instrumentation) has been developed to treat degenerative disc disease in the cervical spine. The prosthesis design incorporates a proprietary, low friction, wear resistant, elastic nucleus. The nucleus is located between, and articulates with anatomically shaped titanium plates (shells) that include porous ingrowth surfaces to allow bony fixation to the adjacent vertebral end plates. The design provides for normal range of motion in flexion/extension, lateral bending, rotation and translation. While prosthesis motion is relatively unconstrained through the normal range of motion, special geometric features provide soft limits to this range. The implant design also incorporates a unique flexible membrane that surrounds the axially symmetric interior articulating surfaces to prevent migration of any articular wear debris and separate the internal structures of the device from the external *in vivo* environment. A patented instrumentation system achieves precise preparation of the vertebral body endplates and provides accurate alignment and placement of the device.

Extensive laboratory and animal testing was performed to adequately determine and demonstrate the safety of the functional cervical disc prior to initiating clinical trials. *In vitro* testing, including static and fatigue evaluations, was conducted on the components, subassemblies and final devices to evaluate and establish the prosthesis' mechanical performance limits under "worst case" conditions. This testing included evaluation of prosthesis stability in a variety of loading scenarios utilising a mechanical cervical spine simulator to determine the long-term functionality and durability of the prosthetic system. This simulator subjected the device to dynamic load and motion profiles representative of normal *in vivo* conditions. Other bench and cadaver studies were conducted that included testing to ensure the functionality of the surgical instrumentation system.

Pre-clinical animal studies were conducted to study the *in vivo* performance of the prosthesis and the surgical instrumentation. An adult chimpanzee model was selected as the most appropriate because of its similarity to the human in cervical spinal anatomy, morphology, and biomechanics. Three independent studies evaluated device safety in a total of 12 animals with up to six months follow-up. The results showed that the prosthesis was stable, did not subside or migrate, and provided motion at the operated level. Fluorochrome labeling demonstrated bone

ingrowth into the prosthesis shells. When combined with extensive *in vitro* testing, these robust chimpanzee study results collectively demonstrated device safety and supported the initiation of clinical trials.

A multicentre clinical trial was initiated in January 2000 to assess the safety and effectiveness of the prosthesis in treating cervical degenerative disc disease compared to ACDF. Patient inclusion criteria for the study were disc herniation or spondylotic changes at the C3-C4 to C6-C7 levels with radiculopathy and/or myelopathy that had not responded to conservative treatment. The efficacy of the device was assessed by evaluation of each patient's pain, neurological function and range of motion at the implanted level. To date, six centres throughout Europe have implanted 64 devices. One-year follow up has been completed on six patients, all of whom had excellent results. Of the 23 patients clinically assessed at the six-months follow up period, 92% had good to excellent overall results. Analysis of the radiographs at the six and twelve-months period showed no subsidence or migration of the device and motion at the implanted level.

While these results are early and the number of patients is limited, the Bryan™ Cervical Disc prosthesis shows promise as an alternative to fusion and its associated complications and morbidities for the treatment of degenerative cervical disc disease.

THE EFFICACY OF A STAND-ALONE CERVICAL CARBON FIBRE CAGE. A RETROSPECTIVE ANALYSIS

M. Rogers

Suite 22 Cabrini Medical Centre, Isabella Street, Malvern 3144

Introduction

For over 45 years a number of different surgical techniques have been utilised in the cervical spine for anterior decompression of the spinal cord and nerve roots to treat compressive radiculopathy and myelopathy. These have included discectomy plus bone grafting and discectomy, bone grafting and anterior plating. Recently interbody cages have been introduced for use in the cervical spine as an adjunct to bone grafting. The Novus Cervical Smith Robinson Carbon Cage (CSR-C) (Sofamor Danek) is one such device that has been employed in one and two level stand-alone fusions.

This study is a retrospective review of patients undergoing implantation of this prosthesis assessing fusion rates, bone graft donor site (iliac crest) pain and post operative dysphagia.

Methods

Forty four patients had 50 cages implanted over an 18 months period (January 1999-June 2000). Thirty eight patients had a single level fusion, eight had a two level fusion. Six patients had myelopathy due to cord compression at one level only the remainder of the patients had radiculopathy. CSR-C cages of varying heights were used (5, 6, 7 or 8 mm). Autologous cancellous bone was obtained from the iliac crest in all cases. Lateral and A-P radiographs were obtained in all patients at day one, week four and week 12 post-surgery and were assessed for interspace height, fusion rate and retro or ante pulsion by independent Neuro-radiologists. Bone donor site pain was assessed using a visual analogue scale at day two and week four and compared with scores obtained previously from patients having bone only or bone and plate fusions. Dysphagia was assessed at weeks four and 12 using a four point questionnaire.

Results

The fusion rate at three months based on lateral radiographs was 98%, there was one case of decreased interbody height, there was no evidence of cage movement. Bone donor site pain was less severe and frequent at week four and 12 when compared to the previously operated groups. Dysphagia was a problem to two

patients at week four and at 12 weeks had completely settled. No patient was worse neurologically and there was one minor wound infection.

Discussion

Stand-alone radio-lucent cervical interbody cages appear to be a satisfactory adjunct to anterior cervical decompressive surgery. The fusion rate is comparable to that seen with tri-cortical autologous graft and plate fixation. There appears to be less patient morbidity associated with this technique and it is safe. Whilst other technologies which may not require bone to achieve fusion or do not employ fusion are being trialed prospective studies using this prosthesis should be considered.

PLIF AND CORRECTION OF SAGITTAL DEFORMITY FOR SPONDYLOLISTHESIS – EVOLUTION OF A TECHNIQUE

W. Sears* and P. McCombe**

*Department of Neurosurgery, Royal North Shore Hospital, Sydney, Australia and

**Department of Orthopaedics, Royal Brisbane Hospital, Brisbane, Australia

Introduction

Techniques of Posterior Lumbar Interbody Fusion (PLIF) have changed and its popularity has fluctuated over the years. The surgical reduction of spondylolisthesis with attempted complete correction of the sagittal deformity and stabilisation using pedicle screw instrumentation and wedge shaped interbody spacers is a relatively new technique, developed by Dr Arthur Steffee and modified by the authors.

A review was undertaken of 100 consecutive patients with isthmic or degenerative lumbar spondylolisthesis for whom follow-up data were available and who were managed with this technique between October 1993 and April 2000.

The purpose of this review was to determine the efficacy of the technique and attempt to identify those factors which have contributed to the patient outcomes.

Methods

All patients were operated upon by the first author. Patient pre-operative, operative and post-operative data and complications and follow-up Surgeon Subjective Outcome Assessments (SSOAs) were acquired prospectively. Retrospective questionnaires seeking Patient Subjective Outcome Assessment (PSOA) were sent to all patients and the responses compared with the SSOAs. A model correlating the SSOA with the PSOAs was created and used to produce a transformed or corrected outcome score: 4=excellent, 3=good, 2=fair, 1=unchanged, 0=worse, -1=death. The patients were separated chronologically into three groups of equal size. Mean outcome scores and complication rates for the three groups were compared.

Results

There were 45 patients with degenerative and 55 with isthmic spondylolisthesis. Mean follow-up time was 48 months and a minimum of nine months. 36 patients from the study and an additional six more recent spondylolisthesis patients responded to the questionnaire. Comparison of the PSOAs with SSOAs yielded a model of $PSOA = 1.58 + 0.52SSOA$ (Pearson Correlation of 0.55 and variance of 30%). The SSOA tended to overestimate the number of excellent and poor outcomes when compared with the PSOAs.

Mean transformed outcome score for the first 33 patients was 3.01, second 33 was 3.30 and third 34 was 3.43. The difference between the first and third groups was significant (t test, $p < 0.05$).

Good or excellent outcomes were obtained in 62.5% of the first group, 78% of the second and 91% of the final group. No patient in the final group was made worse and only one reported no improvement.

Prior to January 1995, the interbody grafting was done using morcellised posterior elements only and no posterior graft. Five of 27 patients (19%) operated upon using this technique developed a non-union. Subsequently, the interspace was

supported with wedge shaped carbon-fibre spacers with serrated upper and lower surfaces. The interbody graft was supplemented with additional iliac crest cancellous bone and the posterior elements were also grafted. Two of the following 73 patients (3%) developed a non-union.

Discussion

The use of lordotic intervertebral spacers, the conservative removal and grafting of the posterior elements as well as improved patient selection have resulted in a significant improvement in clinical outcomes over the last 6½ years. While technically difficult, this PLIF technique now yields a high fusion rate, correction of sagittal and coronal deformity and a high rate of good or excellent clinical outcomes.

SHOULD POSTEROLATERAL FUSION BE ADDED TO POSTERIOR LUMBAR INTERBODY FUSION?

P. McCombe and S. Wordsworth

Introduction

Posterior interbody fusion can be performed with and without posterior instrumentation and with and without posterolateral or posterior fusion. When a solid anterior interbody graft/implant is present there may be no need for a posterolateral fusion and a posterior facet fusion may make more biomechanical sense. Avoidance of the extra dissection and retraction of a posterolateral fusion may reduce pain associated with retraction damage and denervation of the posterior muscles. This study aims to compare the outcome of instrumented posterior interbody fusion with and without posterolateral fusion.

Methods

A series of 50 consecutive cases of posterior lumbar interbody fusions were analysed retrospectively. All cases were performed using carbon fibre PLIF cages or ramps with pedicle screws and autologous graft. The indications were back pain and leg pain due to neural compression associated with instability, due to spondylolisthesis, degenerative scoliosis, loss of disc height or after failed discectomy. Forty-three cases (86%) were able to be followed by questionnaire to determine pre- and postoperative visual analogue pain score, EuroQol quality of life score, and operative satisfaction. The first 18 cases had associated posterolateral fusion (mean follow-up 40 months) and the following 25 cases (mean follow-up 24 months) did not have posterolateral fusion. The two groups appeared to be of similar ages (59.4 and 58.7 years) and to have similar preoperative pain (7.6 and 6.0) and EuroQol Scores (4.6 and 4.0).

Results

Analysis showed that there was a statistically significantly higher percentage improvement ($p = 0.0009$) in postoperative visual analogue pain score in the group without posterolateral fusion (68.8%) compared to the group with posterolateral fusion (34.5%). There was also a significantly higher ($p = 0.008$) percentage of patients who expressed satisfaction with their operation without posterolateral fusion (96%) compared to the group with posterolateral fusion (66%). The EuroQol score improved more without posterolateral fusion (2.9) compared with posterolateral fusion (1.5) though this was not statistically significant ($p = 0.1$).

Discussion

The results suggest that posterolateral fusion is unnecessary in this group of patients and that it may adversely affect outcomes. The most likely explanation for the difference in outcome is that the technique of posterolateral fusion causes permanent pain by retraction damage and denervation of the posterior muscles.

POSTERIOR OCCIPITO-CERVICAL SURGERY

F.J. Eismont

University of Miami School of Medicine, Department of Orthopaedics & Rehabilitation, Miami, Fl.

Introduction

The basic principles in occipito-cervical surgery are to perform a normal decompression and then stabilise the spine. The decompression is often a combination of a reduction, a laminectomy, and/or a suboccipital craniectomy. If the patient has cervical myelopathy and instability the plan is always to perform a posterior decompression and stabilisation and perform an anterior decompression only if there is no improvement clinically. Bone graft sources for occipito-cervical fusion include autogenous iliac bone graft, calvarial bone graft, cadaver graft, and combinations of the above. In 1985, I published a review of seven allograft fusions in children and all seven developed nonunions in the posterior cervical spine. In 1991, we had presented our data of thirty patients who had undergone posterior occipito-cervical fusion for non-rheumatoid pathology using no plates/screws. All of these patients were kept in a halo for three months and one patient required revision surgery at one day for a broken graft and all thirty patients developed a solid fusion. The goal of the current study was to compare surgery using plate and screws with the previously described group of patients. This group included twenty-four patients treated with autogenous graft in all cases and with additional allograft in some of the cases. Plates, screws and cables were used in all patients. A collar was used for 0 to 12 weeks. Two patients required halos because of severe degrees of instability.

Results

One patient required repeat operation for an infection. All twenty-four patients developed solid fusions. The average time of immobilisation was fourteen weeks for those two patients who required halo vest immobilisation and nine weeks for those patients who were treated in a rigid collar. The complications include the one infection, and there were two deaths at one month and six months in patients who had cancer. These patients died as a direct result of their cancer. There were no broken plates or screws and no broken cables.

Discussion

The type of plate or plates used dictates the surgeon's major concerns. These include stability, ease of application, cost, and the risk of complications including bleeding, spinal fluid leaks, and plate loosening. It is important that solid "anchor" screws are utilised. These are ideally C1-2 transarticular screws or C2 pedicle screws. Skull osteology has been researched by Roberts et al in 1998 and their information will be presented. The technique utilising bilateral plates will be illustrated. Other options which can be considered include: screws in the C1 lamina, screws in the posterior C1 lateral mass (Harms technique), and lateral C1-2 transarticular screws (Whitesides technique). Primary principles of occipito-cervical surgery remain the same: decompression and stabilisation. These were achieved in our earlier review with thirty of 30 patients achieving a solid fusion. This was also achieved in our more recent review with twenty-four of twenty-four patients achieving a solid fusion. The primary difference is that the earlier group had to be immobilised in a halo vest and only two of twenty-four patients in the latter group required a halo vest. As surgeons we need to make the final decision and do what is necessary to achieve a good result – no more, no less.

AUTOLOGOUS GROWTH FACTORS: CHARACTERISATION AND CLINICAL USE

D.M. Arm, M. Ponticello and E.C. Shors
Interpore Cross International, Irvine, CA USA

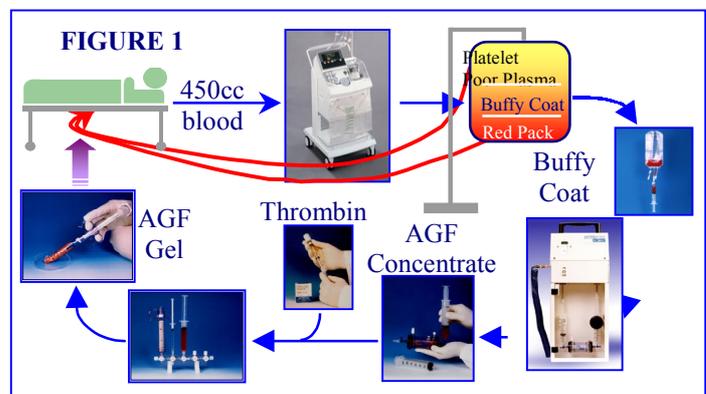
Introduction

One of the holy grails of orthopaedics is to enhance bone regeneration by the use of growth factors. An intra-operative technique of collecting and concentrating the buffy coat (platelets and white cells) from the patient's own blood has been developed. This autologous approach may be an alternative to other potential osteoinductive therapies such as bone morphogenetic proteins. Platelets contain a number of growth factors, including PDGF, TGF- β , FGF, IGF, and VEGF, which have been demonstrated to have an active role during various stages of the bone healing cascade. These factors have been shown to enhance vascular tissue ingrowth, increase the migration of osteoblasts and osteoprogenitor cells to the local site, cause these cells to multiply in number, and influence their differentiation down the osteoblast lineage progression. Termed Autologous Growth Factors™ (AGF™), this ultraconcentrated material also contains elevated fibrinogen levels, and will form a reliable, firm gel upon the addition of thrombin. This study details an *in vitro* characterisation of several of the growth factors contained in AGF, and discusses its current clinical experience.

Methods

450 ml of human blood was run through a Haemonetics Cell Saver® 5 to separate the buffy coat. A centrifuge speed of 5600 rpm was used to fill the bowl with red cells and draw off the platelet poor plasma. The bowl was slowed to 2400 rpm to collect the buffy coat (BC). 150 ml of BC was then concentrated using an UltraConcentrator (Interpore Cross) to 60 ml of AGF concentrate. A schematic of this process is shown in Figure 1.

Samples were taken from the blood, BC, and AGF for platelet counts on a Coulter AcT-10, and ELISAs were performed on PDGF, TGF- β , VEGF, bFGF, and EGF (R+D Systems).

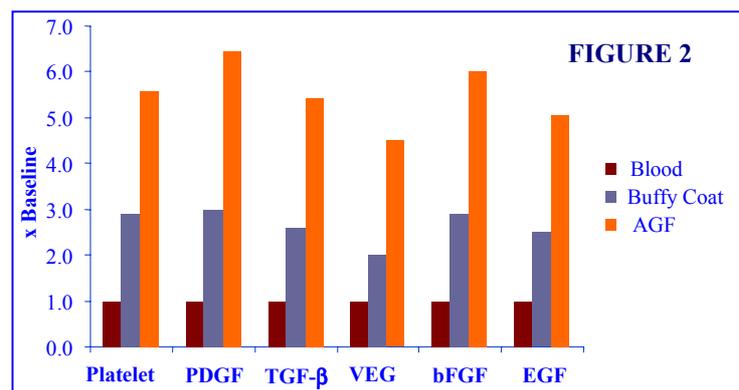


Results

Growth factor concentrations consistently increased 5-7x over baseline levels in blood, as shown in Figure 2. Increases in growth factors corresponded to the increase observed in platelet concentration. Fibrinogen concentration in AGF was 6.9 mg/ml, a 2.5x increase over both blood and buffy coat (2.7 and 2.8 mg/ml, respectively).

Discussion

AGF looks to be a promising material to provide the patient's own growth factors for tissue regeneration applications. Further benefits include improving graft handling and minimising migration. To date, over 15,000 cases have been performed using AGF in the United States, in spinal fusion, total joint revisions, non-unions, and other indications. While prospective studies are under way, anecdotal results and retrospective analyses have been very favourable.



SPINAL FUSION USING AUTOLOGOUS GROWTH FACTOR

M. Scott-Young

Gold Coast, Australia

Introduction

The purpose of this study is to determine whether or not autologous growth factor has an adjunctive role in accelerating and enhancing spinal fusion radiographically and clinically.

Methods

The data collected for this study comes from the surgical experience of one orthopaedic surgeon and was collected from the patient's post-operative clinical and radiological results.

Results

Of the 69 patients included in the study, 86% had a good to excellent result, 20% had a satisfactory result, and 4% had an unsatisfactory result. The results were determined on the basis of the radiographic evidence being analysed by a radiologist and patient results being interpreted with clinical surveys, SF36 data, and visual analogue scores.

Discussion

This is a prospective and ongoing study looking at the ease of application, the clinical consequences, and complications associated with the use of autologous growth factor. The vital role played by local growth factors in the complex series of events which lead to bone healing and grafting incorporation is discussed. The various biological factors which initiate, maintain, and regulate the complex processes of osteogenesis are reasonably well understood. A major concern in delivery of the growth factors to the site of bone healing is that they have short half-lives and systemic circulation. This paper discusses the preparation of autologous growth factor concentrate and discusses the issue of whether the application of growth factors promotes early maturation of bony fusion.

The cases involved in this study vary from 16 months post surgery to two months post surgery, with nine months on average. Radiological analysis took place post-operatively and at six weeks, three months, six months, and nine months. At this stage, there were no pseudarthrosis, no reabsorption, one infection, and two hardware failures. The average age is 60.6 years. In the population pool, 15% were smokers and 5% were insurance or workers' compensation cases. All had autograft, autologous growth factor and Pro-osteon applied to their fusion. In 40% of the cases, allograft was used to increase the bulk of the fusion mass. All patients had cell saver techniques utilised. The cases included the following procedures and instrumentation:

No.	Procedure	Instrumentation
41	PSF	Pedicle screw system
9	PSF & ALIF	Iliac crest allograft and pedicle screw system
1	ALIF	Lordotic cage
10	PSF & PLIF	Pedicle screw system and carbon fibre cage
5	PCF	Lateral mass plate
3	ACF	(Vertebrectomies) 3 interbody cages, 2 anterior cervical plates

EXPERIENCE WITH OP-1 IN HUMAN INTERBODY SPINE FUSION

P. McCombe and B. Walsh

Introduction

Osteogenic protein 1 (Bone Morphogenetic protein 7) is a recombinantly produced human growth factor that is a potent osteoinductive agent. In long bones in animals and humans the material has been shown to bridge critical sized defects. The

material seems to be at least as potent in repairing nonunion of human tibial fractures as autogenous graft. In sheep and baboons the material had been shown to promote interbody bone formation in the spine. This paper investigates the use of OP-1 to cause fusion of the interbody space in humans.

Methods

A pilot study was undertaken to identify the effectiveness of OP-1 putty (OP-1 with collagen carrier and carboxymethylcellulose binding agent) used with a carbon fibre composite cage inserted laparoscopically into the L5/1 disc space. It was planned that 10 cases be implanted and that the results be compared to a historical series of 15 cases of the same procedure with autograft, which had shown acceptable clinical and radiological results. Radiographic follow-up with x-rays and DEXA was performed at four weeks, 12 weeks, six months and 12 months. Functional outcome was obtained by self-assessment with SF12 health outcome, and the Low Back outcome score.

Results

The trial was suspended after five patients because of poor clinical results and an apparent failure to form bone. Of the five patients implanted one had an outstandingly good clinical result, one patient had an acceptable result and three patients had poor results with two patients with worse pain. A feature of the poor results was that the pain was worse in the erect posture, suggesting a mechanical problem. Serial radiographs failed to show significant bone formation up to 12 months. DEXA scans have shown no significant change in bone mineral density. Some settling of the cage into the end plate was seen in all cases. Mechanical testing of the carbon cage was performed to identify any difference in load bearing properties of the cage with autograft compared to the cage without autograft. Implants were compressed against foam blocks of various densities to approximate the mechanical properties of normal and osteoporotic bone. Analysis of the load displacement curves showed more collapse into the end plate in cages without autograft compared to cages with autograft in lower foam densities.

Discussion

Osteogenetic proteins cause bone formation by stimulation of local tissue stem cells to differentiate into osteocytes in a favourable mechanical and biological environment. Possible reasons for the observed failure are considered either to be biological or mechanical. The likely biological factor is probably an inadequate source of stem cells. The likely mechanical factor is the observed difference in load sharing between a cage with autograft and a cage alone. Anecdotal evidence suggests that OP-1 causes bone formation in posterolateral fusions in humans and that interbody bone formation has occurred within a threaded titanium cage. The Interbody site does not have a muscle envelope (such as in the posterolateral site) from which to gain access to stem cells. The only source of local stem cells seems to be from the adjacent bony end plate. Perhaps the process of reaming into the cancellous bone of the body in a threaded fusion cage may gain extra access to stem cells.

AUTOLOGOUS GROWTH FACTORS FOR USE IN SPINAL FUSION

W.R. Walsh, A. Loeffler, S. Nicklin, D. Arm and Y. Yu

Orthopaedic Research Laboratories, Prince of Wales Hospital, University of New South Wales, Sydney, Australia

Introduction

Resorbable ceramic biomaterials are osteo-conductive based on their ultrastructure and biochemistry, but lack inductive or osteogenic factors. Platelets contain a number of factors implicated in fracture healing and bone repair, including platelet-derived growth factor (PDGF) and transforming growth factor beta (TGF- β). This study examined the effects of platelet and WBC sequestration and concentration

(Autologous Growth Factors™, AGF™, Interpore Cross International) in combination with a resorbable porous calcium carbonate-hydroxyapatite bone graft substitute (ProOsteon 500R), marrow, or autograft in an aged ovine posterolateral spinal fusion model.

Methods

Surgery: A standard L3-L4 posterolateral pedicle screw fusion model was used in twenty-four five year old ewes using ProOsteon 500R with AGF, ProOsteon with AGF and marrow aspirate, autograft with AGF, or autograft alone (six per group). Animals were anaesthetised and 400-450 ml of blood was withdrawn. 60 ml of buffy coat was isolated using a two-stage sequestration protocol using a Medtronic Sequestra 1000. Buffy coat was further processed into 20 ml of AGF using an Interpore Cross UltraConcentrator. AGF was added to the ProOsteon or autograft by simultaneous injection with thrombin (100 units/ml).

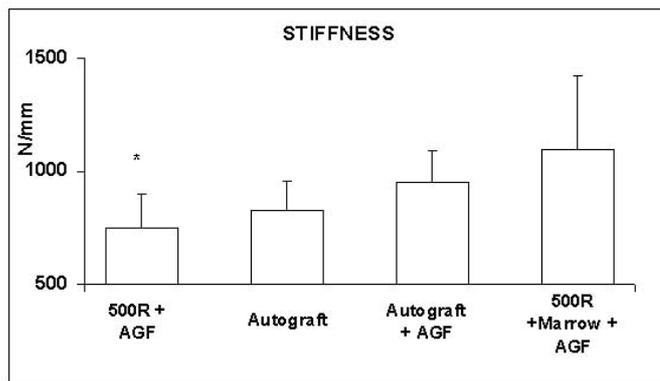
Radiology and mechanical testing: Animals were sacrificed at six months. The L2-L5 segments were harvested for radiology (x-rays, Faxitron). Dual energy x-ray absorptiometry (DEXA) was performed with the small animal software program with a LUNAR DPXL system. Computer tomography (CT) was performed on two animals from each group. Three-point posteroanterior mechanical bending at 50 mm per minute was used to determine ultimate load, stiffness and failure site. Data was analysed using ANOVA followed by a Tukey- HSD test.

Histology/Immunohistochemistry: The spines were fixed in buffered formalin, decalcified in 10% formic acid formalin and paraffin embedded. 5 µm sections were stained with H&E for microscopic examination. Immunohistochemistry was performed using polyclonal anti-human BMP 2, 4 and 7 as well as PDGF and TGF-β. Non-immunised mouse and goat IgG were applied as negative controls.

Results and Discussion

All animals tolerated the procedures without complication. Platelet levels revealed an 7-10 fold concentration in all animals over whole blood. Faxitron radiographs provided excellent visualisation of the fusion masses demonstrating resorption of the calcium carbonate phase of ProOsteon 500R at six months, with new bone formation observed at the transverse process interfaces creeping into the centre of the fusion mass along the vertebral body. Although significant new bone formation was noted upon histology, bilateral fusion did not occur in sheep treated with 500R + AGF. The addition of aspirated marrow to 500R + AGF resulted in fusion in 4/6 cases with significant bone formation between the transverse processes. Bilateral fusion was found 4/6 in the autograft group and in 100% (6/6) in the autograft + AGF group. DEXA values did not significantly differ between groups. CT revealed reformed cortices in the middle of the fusion mass in the AGF + 500R + marrow group as well as the autograft groups.

The six months mechanical data revealed the addition of aspirated marrow to 500R + AGF increased the bending load by 25% over autograft and autograft + AGF but was not significant. The addition of AGF to autograft increased the stiffness by nearly 15% compared to autograft alone, while the addition of AGF and aspirated marrow increased the stiffness nearly 50% compared to AGF + 500R (p <0.05).



Histology revealed a complete cortical shell in the autograft, autograft + AGF, and 500R + marrow + AGF groups. Woven bone with haversian remodeling was noted throughout, though the fusion masses had yet to reach complete maturity. The immunohistochemistry supports a very biologically active fusion mass in all groups with all factors demonstrable in the middle of the fusion mass.

Conclusion

Autologous therapy using AGF stimulates healing through a cascading growth factor pathway. Increased stiffness rather than strength is the early benefit following AGF treatment. The difference in stiffness may continue to increase as the fusion masses mature and remodel. AGF provides a biological boost to an osteoconductive bone graft as well as to autograft. The addition of aspirated marrow to 500R + AGF may present a viable alternative to autograft alone.

ANTERIOR INSTRUMENTED FUSION OF THE LUMBAR SPINE IN SCOLIOSIS - ARE INTERBODY SPACERS NECESSARY FOR SAGITTAL PROFILE?

B.A Taylor and G. Etherington

Royal National Orthopaedic Hospital, Stanmore, Middlesex, UK

Introduction

There have been reports of anterior fusion surgery advocating the routine use of interbody spacers in the lumbar and low thoracic spine. In contrast to these, many surgeons feel that the routine use of interbody spacers is not warranted, provided appropriate surgical technique is used for discectomy, screw placement, and solid rod contouring. Rather, the insertion of spacers may hinder correction of the overall deformity. Our hypothesis was that it is possible to create a satisfactory sagittal profile without the use of interbody spacers.

Methods and Results

Study Design: Retrospective examination of x-rays and appropriate notes.

Patients of the senior author who had undergone an instrumented anterior fusion for scoliosis were reviewed. Some of these patients underwent a second stage posterior fusion to the same level distally. Analysis of the x-rays and notes was performed on a group of 27 patients who had undergone their surgery from July 1996 to December 2000. Follow-up varied from six months to three years.

Inclusion criteria: Diagnosis was adolescent idiopathic scoliosis

All surgery carried out by the one surgeon (BT)

Anterior fusion, with a solid rod, extending into the lumbar spine

There were 15 who had anterior fusion only, and 12 who also underwent posterior fusion. The difference between the groups was that of the nature of the curves. One of the patients had the posterior fusion on a second admission for thoracic curve progression after anterior lumbar fusion. Lowest instrumented levels were - 6 to L2, 15 to L3, and 6 to L4.

Variables measured: Assessment of AP and sagittal alignment was made, as was as fusion across the levels. Methods and problems encountered with data collection will be discussed.

Variables were AP Cobb, Sagittal angle variables were (1) L1-S1, (2) TIV-LIV, (3)LIV-S1 (4) L4, (5)S1.

These were compared with previously published data; difficulties in comparison to 'Normal' will be discussed.

Results

There was no incidence of metalware failure, and no bone/screw interface problems. There was no loss of correction in those cases where follow-up was possible. Union was slow compared to some previously published series. Despite a tendency for a relative loss of lordosis across the fusion, overall lumbar lordosis was maintained within accepted values, and the fusion construct angle was within accepted limits. There was minimal change in Cobb angle of the fusion construct with time.

There have been four cases of <25% retro-listhesis at the upper end of the constructs. These have not produced neurological symptoms, but as yet the significance clinically is unknown.

Conclusion

At this stage the authors feel that routine use of interbody spacers is not justified, as complications without their use have not been forthcoming.

INITIAL RESULTS OF ENDOSCOPIC CORRECTION FOR IDIOPATHIC THORACIC SCOLIOSIS

N. Eames and G. Askin

The Mater Children's Hospital and Holy Spirit Hospital, Brisbane, Australia

Introduction

Endoscopic correction and instrumentation of idiopathic thoracic scoliosis has been undertaken by us for the last 12 months. This procedure has shown promising results in early reports and we present our initial experience for the first cohort of 10 patients.

Methods

Between December 1999 and January 2001, ten patients with an average age of 17 years (range 10 to 37 years) have been treated by this technique. Mean follow-up is six months (range 1 to 10 months). All the patients had primary right sided thoracic curves with a mean pre-operative Cobb angle of 51 degrees (range 35 to 76 degrees). The levels instrumented have ranged from T5 to L1 with a mean of 6.5 levels instrumented (range 4 to 8).

The procedure was performed with the patient in the right lateral position with a mean of four portals being used. Single lung anaesthesia was utilised with a mean operative time of 5.9 hours (range 4 to 7 hours). A mean blood loss of 350 mls occurred. Following discectomy, 6.5 mm screws were inserted under image intensifier and endoscopic control. A 4.5 mm rod was secured and compressed. Bone graft taken from the posterior iliac crest (seven cases) or ribs (three cases) were inserted. An intercostal chest drain remained in situ for a mean of 2.5 days. Patients total hospital stay ranged from four to seven days (mean 5.4 days). All patients have been treated in a brace for three months post operatively.

Results

A mean correction of 49% was achieved with a range of 22 to 70%. A reduction in the mean rib hump from 17.5 to 7.6 degrees occurred. Correction has been maintained to date in all patients. One operation was converted to an open procedure due to failure to tolerate single lung anaesthesia. Surgery was postponed in one patient due to aspiration at the time of induction and rib fractures have

occurred in two cases. A chest drain was reinserted in one case due to a pneumothorax.

Discussion

Initial results from this technique have shown satisfactory correction rates and good cosmetic results with early mobilisation. No serious complications have occurred to date. However, a definite learning curve exists for this procedure and early operative times are long.

THORACIC PEDICLE VS PEDICLE/RIB SCREW FIXATION:

M.F. O'Brien, J. Wood, T.G. Lowe, P. Wong, D. Smith, D. Fitzgerald, L.G. Lenke and S.M. Mardjetko
Medtronic Sofamor Danek, Tennessee, USA

Introduction

Recent reports suggest that for thoracic deformity, pedicle screw constructs achieve superior correction. Concerns have been raised regarding the safety of pedicle screw instrumentation in the thoracic spine because of the proximity to the spinal cord, the trajectory of the screws and the small margin for error.

Purpose

To compare the biomechanical strength of a standard Intra-pedicular pedicle screw to an alternative technique for thoracic "pedicle" screw fixation using a "safer" lateral insertion technique.

Materials and Methods

Four fresh-frozen human cadaveric thoracic spines were harvested with the medial 5-6 cm of rib, intercostal soft tissue and the overlying parietal pleura intact. All nonstructural soft tissue was removed. The spines were instrumented on one side with intra-pedicle screws (standard pedicle screws) and on the opposite side using an extra-pedicular technique (pedicle/rib). The extra-pedicular technique utilises an insertion point lateral to that of a standard pedicle screw. The screw is inserted through the transverse process and directed to engage the lateral aspect of the pedicle and the medial aspect of the rib. Finally the vertebral body is engaged. Pilot holes were prepared and tapped for 5.5 mm screws using fluoroscopy to ensure accurate location of both the intra-pedicular and the extra-pedicular screws. Because of the small size of the specimens and the ability to manipulate them easily, complete visualisation of the pedicle was possible in the AP and lateral projection using fluoroscopy. Fixed angle 5.5 mm x 45 mm. M=8 (Medtronic Sofamor Danek) stainless steel screws were implanted. Fluoroscopy was used to verify the location of each screw after insertion. The entire thoracic spine was then potted in DynaCast epoxy. Biomechanical testing was performed on an MTS809 servohydraulic biaxial biomechanical testing system. The screws were pulled out perpendicular to the longitudinal axis of the spine at each level. A loading rate of 50 N/second was utilised. Load versus displacement data were generated. Maximum load to failure and yield strengths were calculated.

Results

55 thoracic screws were placed. 29 screws were intra-pedicular (pedicle) and 26 screws were extra-pedicular (pedicle/rib). Intra-pedicular screws had a maximum load to failure of $1075 \text{ N} \pm 280 \text{ N}$ (SE 55) and a yield strength of $772 \text{ N} \pm$ (SE43). Extra-pedicular screws had a maximum load in failure of $719 \text{ N} \pm 33.8 \text{ N}$ (SE63) and a yield strength of $566 \text{ N} \pm 220 \text{ N}$ (SE41).

Discussion

Anatomic, radiographic and clinical studies have suggested that the use of thoracic pedicle screws is a practical technique. This study was undertaken to ascertain whether a potentially safer, extra-pedicular screw placement more laterally through the transverse process and engaging the lateral aspect of the pedicle and the medial aspect of rib would be a reasonable alternative to a thoracic intra-

pedicular screw. The data in this study suggest that standard thoracic pedicle screws are significantly stronger than extra-pedicular (pedicle/rib) screws in pullout ($p = 0.001$). Additionally there is more variability in screw purchase with pedicle/rib screws as suggested by the larger standard deviation for both maximum load to failure and yield strength when compared to similar values for standard pedicle screws. However thoracic pedicle/rib screws do achieve 70% of the biomechanical strength of standard thoracic pedicle screws. Extra pedicular placement may be a useful salvage technique when intra-pedicular screw placement is not possible or when a more lateral approach is preferred for safety reasons and maximum fixation is not required.

BONE MORPHOGENIC PROTEIN-7 IN SPINAL RECONSTRUCTION - AUSTRALIAN EXPERIENCE

G. Speck
Melbourne Spine Institute

Introduction

Bone Morphogenic Protein-7 or Osteogenic Protein-1 (OP-1) is a naturally occurring growth factor causing osteoblast proliferation and causing differentiation of progenitor cells.

The use of OP-1 in limb fractures has been undertaken over a number of years. Pre-clinical animal studies have been undertaken on the spine. Pilot studies of its use in the spine have been reported and multi-centre studies are underway.

A clinical review of the Australian experience with the OP-1 implant in spinal fusion was undertaken.

Method

All patients having OP-1 implants were recorded as they were used as "Individual Patient use of a device" under Therapeutic Goods Administration Guidelines. Clinical and radiologic review has been undertaken from the treating surgeons records.

Results

Between the years 1997 and 2000, 17 cases of OP-1 implantation in the spine were undertaken.

The anatomic areas fused were cervical spine (four), thoracic spine (two) and lumbar spine (eleven). All patients had at least one previous surgery. The cervical spine re-operations were in the occiput to C2 levels and predominantly on rheumatoid arthritis patients. The lumbar spine patients were generally after instrumented fusions had failed.

Discussion

The use of OP-1 in this group of patients is as part of a salvage procedure. The specific outcomes, both clinically and radiologically, are made difficult by the combination of factors. The presence of significant bone formation with the use of OP-1 in pilot studies and animal pre-clinical trials indicates that it is likely to be a factor in successful fusion.

Further work with prospective multi-centre trials using OP-1 in the lumbar spine is presently underway in the United States and Europe and the results of these should give a better understanding of the use of OP-1 in the spine, both its utility and best application.

A BIOMECHANICAL EVALUATION OF ANTERIOR CERVICAL STABILISATION SYSTEMS

A. Jackowski, D. Clark, M. Atkinson and S. Bellamy
44 Denistone Road, Eastwood, NSW 2122

Study Design

An in vitro biomechanical study

Objectives

Independently to test currently available systems for anterior cervical stabilisation using test procedures conforming to ISO/TC 150/SC5 N127C Static and Fatigue Test Methods for Spinal Implant Assemblies using Corpectomy Models 2a.

Background

Anterior cervical plating systems are frequently used in situations where they need to withstand high forces. However, no independent author has previously compared systems under the rigours of the ISO standard.

Methods

To ensure comparable results of different systems, a review of dimensions of commercially available systems was conducted, resulting in the standardisation of active length of 40 mm.

Tests were performed on the following systems: Caspar Evolution Unicortical and Bicortical Plates (Aesculap), ABC Unicortical and Bicortical Plates (Aesculap), Equinox Monobloc and Equinox compression plates (Stryker Howmedica), Atlantis Fixed Angle Unicortical and Atlantis Fixed Angle Bicortical Systems (Sofamor Danek), Atlantis Variable Angle Plate (Sofamor Danek), Peak and Peak Polyaxial plates (Depuy Motech), DOC anterior rod system (Acromed), Cervical Spine Locking Plate Classic and Cervical Spine Locking Plate Narrow (Synthes).

Forty- five tests were performed in total with n=3 for all systems except the Atlantis Fixed Angle Plate where n=6 due to testing with two lengths of screws.

The systems were tested using an in vitro model of a single corpectomy of the lower cervical spine, with the application of an offset axial load simulating flexion compression bending at a rate of loading of 25 mm per minute. The apparatus used for testing was a JJ Lloyd Universal Testing machine with a 1 kN load cell, calibrated immediately prior to test commencement

Composite test blocks consisting of a sandwich of solid rigid polyurethane foam between two 1 mm thick layers of glass filled epoxy were manufactured by sawbones to have similar physical properties as a cervical vertebra for testing purposes. Each block was of identical size and consistency with two fresh blocks being used for each test. Synthetic vertebrae can be shown to have greater homogeneity of strength and shape as compared to cadaveric specimens.

All systems were applied and tested by the one experienced spinal surgeon.

Results

Bicortical systems were found to be significantly stronger than unicortical systems with significantly greater final yield strengths. The ABC unicortical plate had the greatest mean maximum yield strength of the unicortical systems at 170.3N with the Peak plate being weakest at 95.3N.

The Atlantis fixed angle plate bicortical system with 20 mm screws was the strongest bicortical system at 364.3N mean yield strength; the Evolution bicortical system being the weakest at 141N.

Interestingly, the Atlantis Fixed Angle bicortical system using shorter, 19 mm, screws had a mean yield strength of 292.3N giving the same system a 73N (124.6%) improvement with only 1 mm increment in screw length to 20 mm.

The Evolution unicortical and bicortical, Equinox Monobloc, Equinox Compression, and Peak plates all failed predominantly due to plate deformation. These plates were found on measurement to be the thinner of the plates used at 1.65 mm, 2.1 mm, 1.7 mm in middle part and 1.5 mm respectively.

Fixation with screws in divergent arrangements was found to lead to less screw pull out compared with screws at right angles to the cortical surface.

Discussion

We have independently tested fourteen different anterior cervical stabilisation systems using ISO testing procedures. We believe this to be the first time such research has been performed.

We have demonstrated a wide range in final yield strengths of systems and that bicortical systems are significantly stronger than unicortical.

We have also shown that besides choice of implant the surgeon's correct choice of screw length and direction of screw placement can be critical to the final strength of a construct.

With a mean maximum yield strength of 364.3N the Atlantis Fixed Angle bicortical plate was found to be the strongest construct by far on flexion-compression testing, the next strongest being the Atlantis Variable angle plate at 283.6N

JUNCTIONAL KYPHOSIS ABOVE THE INSTRUMENTATION IN ADULT SCOLIOSIS SURGERY

N. Eames and G. Askin

The Holy Spirit Hospital, Brisbane, Australia

Introduction

In adult scoliosis surgery, it is often difficult to know at which levels to end the fusion. Proximally, the fear of a junctional kyphosis occurring above the instrumentation often leads to an extension of the fusion when planning such surgery. The aim of this paper is to assess if such a deformity has occurred in a cohort of patients with long fusions extending into the thoracic spine.

Methods

A retrospective review of a series of 23 consecutive patients treated by the senior author over the last five years at a single institution was performed. Patients were identified from hospital records and previous x-rays obtained. All patients had undergone posterior fusion and instrumentation for adult degenerative scoliosis. The Cobb segmental angle was measured to assess the degree of junctional kyphosis proximally on the lateral x-rays pre- and post-surgery. This was calculated as the intersection of two lines, one drawn from the superior end plate of the vertebral body above the proximal end of the fixation and the other drawn at the inferior end plate of the vertebral body beneath the proximal end of the fixation.

Results

Two patients could not be located. Nine patients have been unable to locate relevant x-rays to date. Of the remaining 14 patients studied, all had undergone laminectomies at the time of surgery and four had undergone planned additional anterior lumbar fusion. All had undergone posterior fusion with pedicle screws and hooks using the Universal Spine System (Synthes). The mean age was 71.4 years (range 51 to 78 years) and 71% of the patients were female. The proximal limit of the instrumentation ranged from T5 to T12 with 86% being between T8 and T12. The majority of patients were fused to L5 (64%). Mean follow-up was 3 years (range 2 to 5 years).

The mean Cobb segmental angle at the site of the proximal instrumentation measured pre-operatively 20 degrees (range 1 to 11). This fell to 9.8 degrees at one year post surgery (range -3 to 20) and subsequently increased at 2 years post-operatively to 10.5 degrees (range -1 to 25). The mean increased at three and four years respectively to 12.6 and 12.5 degrees. There was, however, no significant difference between the mean values at any of the reviews (range $p = 0.15$ to 0.19). There was no correlation between the level of proximal limit of the instrumentation and the mean change in Cobb angle for that level ($R^2 = 0.16$).

Discussion

There was no statistically significant increase in junctional kyphosis above the proximal extent of the instrumentation, although a small increase in the mean Cobb

angle was observed with time. This provides reassurance that the proximal extent of the fusion in patients with degenerative scoliosis can safely be placed in the lower thoracic spine without a progressive junctional kyphosis occurring above the instrumentation in correctly identified patients.

EVALUATION AND ANALYSIS OF PATIENT OUTCOMES WITH AN INTRASEGMENTAL FIXATION SYSTEM IN LUMBAR SPINAL FUSION

J. Finkenberg, C. Banta, G. Lee Cross III, E. Dawson, D. Gutzman, T. Highland, D. Kucharzyk, L. Lenderman, J. Murphy, W. Neely, A. Rogozinski, C. Rogozinski

Introduction

A new spinal fixation system with polydirectional screws and modular links with interconnecting radial serrations has been developed. The system allows the linking of multiple points of fixation, two points at a time (intra-segmental fixation), thus eliminating the need for intraoperative contouring of rods or plates.

To evaluate this new type of spine system, which was done through biomechanical studies, analysis of lumbar lordosis preservation post-operatively and multicentre review of patient outcomes with a minimum of one year follow-up was undertaken.

Methods

Biomechanical studies of the spine system were performed according to ASTM standards. To evaluate the maintenance of lordosis, radiographs from the first 119 patients were reviewed by the authors. Analysis of patient outcomes consisted of a review of the first 259 patients who underwent spinal fusion surgery with the new spine system.

Evaluation of patient outcomes consisted of 122 men and 137 women with an average age of 50 ± 13 years (range 22-96 years) and a mean follow-up of 20 ± 6 months (range 12-54 months). The patient population was at high risk for fusion failure, with one hundred twenty-seven (49%) smokers, 141 (54%) who had previous spine surgery, 22 (8%) with osteoporosis, 63 (24%) were obese, and 32 (12%) with diabetes. One hundred and two patients (39%) had a one level fusion, 105 patients (41%) had two levels fused, while 52 patients (20%) had three or more levels fused. The majority of patients (66%) were covered under Workers' Compensation.

Radiographic fusion was deemed successful when the presence of trabecular bridging bone from transverse process to transverse process was observed, as well as no fixation failure or radiographic evidence of screw loosening. Clinical success was rated excellent, good, fair or poor depending on the patient's pain level, function, and pain medication intake.

Results

Biomechanical studies of this intra-segmental fixation system have shown it to be strong under both static and fatigue testing, with exceptional strength in compression bending. In evaluating preservation of lumbar lordosis, no statistically significant loss of lordosis was observed. Overall, radiographic fusion was noted in 229/259 patients (88%), and did not differ significantly ($p > 0.10$) by the number of levels fused, while clinically, 69 patients (27%) had an excellent result, 111 patients (43%) had a good result, 50 patients (19%) had a fair result and 29 patients (11%) had a poor result. The high rate of successful patient outcomes did not differ significantly ($p > 0.10$) by the number of levels fused, or other patient or surgical variables, except for the satisfaction level of Workers' Compensation versus Non-Workers' Compensation. One hundred of 118 patients (85%) who were working prior to surgery returned to work at an average 9 ± 4 months post-operatively (range 2-20 months). The use of DC stimulation in this population was reserved for patients with one or more risk factors for fusion failure, and was noted to be of benefit. There were no recorded intraoperative complications but post-operatively five device and 19 non-device related complications (9%) were noted, which is comparable to other lumbar fusion series.

Discussion

The results of these analyses show consistent patient outcomes regardless of the number of levels fused with an intrasegmental system. This may be attributable to the increased biomechanical strength of the system at each segment, coupled with the ability of intrasegmental fixation to maintain sagittal plane balance through preservation of the patient's lordotic curve.

WOUND INFECTION IN SPINAL FUSION SURGERY

J.E. Ricciardi, M. Atkinson, T.S. Whitecloud III and W. Roesch

Introduction

Post-operative wound infections are more common in adults undergoing spinal fusions and occur more frequently in instrumented than in un-instrumented procedures. Changes were instituted in our operating room procedures and in our techniques of wound management to attempt to reduce our incidence of post-operative wound infection.

Method

A retrospective, computer data-base review of all adults undergoing thoracic, thoracolumbar, and lumbar instrumented fusions from July 1994 to July 1999 was conducted.

Conclusion

1. Patients undergoing anterior/posterior spinal fusion procedures have a higher risk of wound infections (4/159) than those having posterior only procedures (4/221).
2. Anterior wound infections are uncommon in patients undergoing either combined anterior/posterior or anterior only spinal fusion procedures.
3. Simple changes in wound management, a commitment by the surgical team to practise strict sterile technique, and changes in OR procedures can lower the incidence of post-operative wound infections in adults undergoing instrumented spinal fusions.

¹ Goffin, Geusens, Vantomme, Quintens, Waerzeggers, Depeitere, Van Calenbergh and Van Loon (Leuven, Belgium): "Long-term Follow-up After Interbody Fusion of the Cervical Spine". Presented at the Twenty-Eighth Annual Meeting of the Cervical Spine Research Society; Charleston, South Carolina. November 30, 2000.