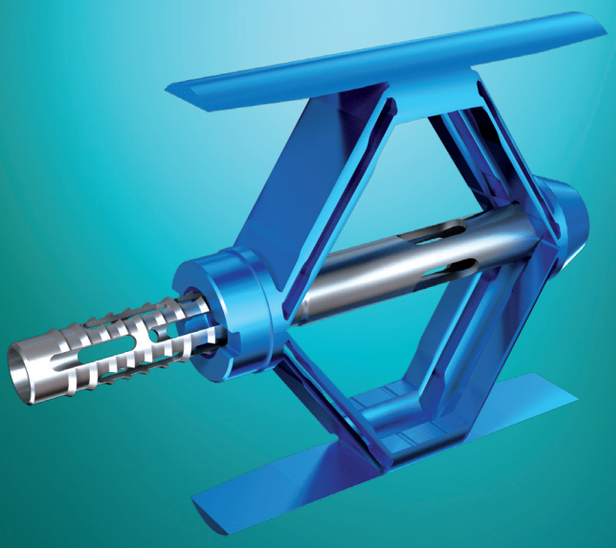

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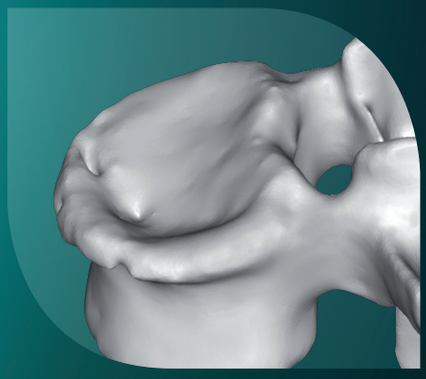

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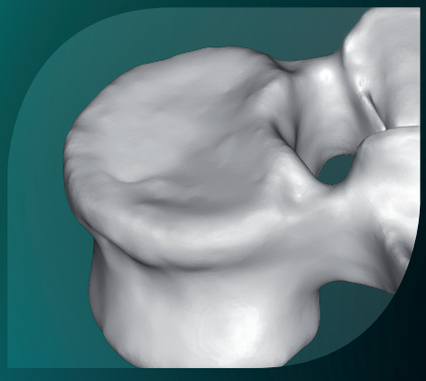

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Vertebral anatomical restoration before fixation as a new method to treat vertebral compression fractures.

David NORIEGA

Stryker Spine International Symposium / April 16th - April 18th, 2009. Barcelona, Spain

Introduction

Surgical treatments for bone fractures in lower and upper limbs usually involve a two-step procedure: Anatomical reduction and Fixation while maintaining the reduction, to be able to restore the function without a deformity.

Even if literature exists on the importance of endplate reduction in Vertebral Compression Fractures to avoid complications, there is currently no clear evidence of anatomical reduction of the VCF (involving anatomical endplate reduction) prior to their fixation using the existing techniques.

For many years, the gold standard technique for Vertebral Compression Fractures has been vertebroplasty. But optimal positioning of the patient during surgery cannot provide endplate restoration since no mechanical effort is applied onto the vertebral endplates.

More recently, the balloon kyphoplasty gave the possibility to act directly onto the vertebral body and endplates by inflating a balloon inside the vertebral body prior to cement injection. This technique is limited by the fact that balloons are removed prior to cement injection. Therefore, the reduction cannot be maintained while cement injection and there is a loss of fracture reduction while removing them. Moreover, there is no reliable means to control the manner the balloon will expand in the vertebral body.

The aim of this study is to assess the ability of a new Vertebral Cranio-Caudal Expandable Implant (VCCEI) called SpineJack® to reduce anatomically and in a controlled manner the vertebral fracture prior to its fixation.

Method

15 patients (Mean age: 46,8 years old, gender : 10F/5M) involving 17 VCF (13 single level and 2 double levels) were included in a prospective study. The surgical procedure was performed percutaneously by transpedicular approach and 2 Titanium VCCEI were positioned below the fractured area under fluoroscopic guidance. The unique design of the implant allows the surgeon to apply cranio-caudal forces to reduce A1, A2 or A3.1 VCF without any ventral-dorsal forces in order to prevent any bony fragment from being pulled out. After expansion, the implants were left in the vertebral body so that the reduction was maintained for all the injection duration phase. All the treated vertebrae were then reinforced with PMMA cement.

Vertebral volumes, heights restoration, endplates' angles changes and implants' position with the volume of injected cement were obtained thanks to CT scans made prior to surgery (inclusion visit) and after the treatment (discharge). VAS score was evaluated during this study.

The CT scan data were analyzed by an independent laboratory (LBM, ENSAM – PARIS) to build a 3D reconstruction of the involved vertebra prior and after the surgery.

The two 3D reconstructions were superimposed using a validated matching algorithm based on anatomical points on the posterior arch to evaluate the study parameters.

Patients were asked to evaluate their pain using the VAS score at each step of the evaluation schedule.

Results

The SpineJack® implant allows achieving anatomical vertebral body reduction thanks to an anatomical restoration of the injured endplate as well as a kyphotic angle improvement by 58%, a vertebral body volume (+10,6% volume augmentation) and height increase (Mean : 3,1 mm, Min : 0,4 mm – Max : 10,8 mm) without any antepulsion or retropulsion of fragments.

Conclusion

This new intravertebral reduction-reinforcement procedure has shown clinical and radiological effectiveness in achieving anatomical reduction of VCF as well as reducing patients' pain. This technique should enhance long-term clinical results as it allows limiting disc creeping or progressive kyphosis following disc collapse often observed when there is no endplate anatomical restoration.

Prospective clinical and radiological analysis of vertebral compression fractures (VCF) treated by an intravertebral reduction-reinforcement procedure.

David NORIEGA

AOS / June 23rd - June 26th, 2009. Las Vegas, USA

Objective

1.Illustrate clinical results when treating VCF by anatomical reduction and fixation

2. Illustrate CT scan 3D reconstruction to show endplate and anatomical reduction of VCF.

Background summary

Literature exists on the importance of endplate reduction in VCF to avoid complications like disc creeping, progressive kyphosis following disc collapse, facet joints' arthritic-degeneration at the above level and compensatory hyperlordosis with all symptoms it includes.

Material and method

16 patients with VCF were included in a prospective study. The surgical procedure was performed by transpedicular approach and 2 titanium implants were positioned below the fractured area under fluoroscopic guidance. The expansion system of the implant allows applying cranio-caudal forces (never ventral-dorsal forces) to reduce A1, A2, or A3.1 VCF. The vertebra is then reinforced with PMMA cement.

In order to evaluate the reduction on vertebral endplates, CT scans were taken and analyzed by an independent laboratory (LBM at the ENSAM Paris). Their method allows quantifying vertebral volumes and heights restoration, endplates' angles change and implants' position with the volume of cement inserted.

Results

This surgical procedure allows achieving endplates' reduction, kyphotic angle improvement, vertebral volume and height increase without retro-pulsion and ante-pulsion of fragments.

In order to exclude inter-analysis variability, pre and post op 3D reconstructions of CT scans were positioned and analyzed according to fix anatomical points on the vertebral posterior arch.

Conclusion

This surgical procedure has shown clinical and radiological effectiveness in achieving anatomical reduction of VCF and in improving patients' pain score and quality of life.

The analyzing method developed by the LBM has proven precision and reproducibility in analyzing and quantifying anatomical reduction of VCF.

A new device for percutaneous vertebral re-expansion. Preliminary experience on 23 patients for Magerl type A traumatic burst fracture.

Xavier BARREAU

World Federation of Interventional and Therapeutic Neuroradiology / June 29th - July 1st, 2009. Montreal, Canada

Objective

To evaluate height restoration of fractured vertebrae post operatively and after 6 months after kyphoplasty using a permanent intravertebral implant combined with PMMA.

Material and method

23 patients were prospectively included after a spinal traumatic event and CT scan showing evidence for thoracolumbar compression fracture without osteoporotic background. All fracture types were A1 to A3.1 according to MAGERL classification. No patient had posterior arch involvement. All patients were treated before within 10 days post trauma. 2 implants were used at each level. CT scan were performed after surgery and 6 months later. Several quality of life questionnaires were performed before treatment and 6 months later. All data were collected and analyzed in an external statistical unit.

Results

26 vertebrae have been treated in 23 patients. Mean height restoration at anterior part of vertebra was 2,2mm and 2,3 mm at the mid portion. No complications have been observed. All patients could stand up the day after treatment. Mean time to discharge without brace was 3,2 days. Vertebral pain assessment showed reduction from 7,1/10 to 2,1 at day 1. All quality of life indicators showed dramatic improvements during all the follow up.

Conclusion

The use of SpineJack® implant in burst fractures allows quick discharge of patient and satisfying restoration of vertebral height after 6 months. The safety of procedure must lead to a comparative study versus orthopedic and/or surgical treatment.

A new device for percutaneous vertebral re-expansion. Preliminary experience on 23 patients for Magerl type A traumatic burst fracture.

Xavier BARREAU

North American Spine Society / November 10th - November 14th, 2009. San Francisco, USA

Background Context

Treatment of thoracolumbar stable burst fractures classically requires bed resting and bracing. Recently, balloon kyphoplasty has been proposed for acutely fractured vertebrae to increase vertebral height restoration compared to orthopedic treatment. We propose a new minimally invasive technique for vertebral re-expansion using a permanent vertebral cranio-caudal expandable implant (VCCEI) combined with PMMA injection. The goal of this technique is to provide optimal height restoration, as well as strong enough vertebral support to avoid bracing and allow quick discharge.

Purpose

The purpose of this study is to evaluate the anatomical restoration of fractured vertebrae at discharge and 6 months after surgery using a VCCEI associated with PMMA injection.

Patient Sample

23 patients without osteoporotic background and whose CT scan showed evidence for thoracolumbar compression fracture (A1, A2, A3.1) were prospectively included after a spinal traumatic event.

All patients underwent a percutaneous procedure using a VCCEI within 10 days post trauma (20 single level, 3 double level).

Outcome Measures

CT scans were performed prior to surgery, at discharge and at 6 months follow-up.

Clinical data such as VAS score, pain medication, and time to discharge were also collected before and after surgery.

Method

All data were collected and analyzed by an external statistical unit.

Height restoration was calculated using the 9 points method based on measurement of specific anatomical points.

A new method using pre- and post-op CT Scans has been developed by the LBM-ENSAM (PARIS) allowing vertebral 3D mapping and assessment of height restoration after surgery.

Results

No complication has been observed for any of the patients.

VAS score showed a pain reduction from 7,1 to 2,1 on average after surgery associated with pain medication reduction.

Mean time to discharge without brace was 3,2 days.

Mean height restoration at anterior part of vertebra was 2,3 mm (min:0,1mm/max:7,2mm) and 2,4 mm (min:0,1mm/max:6,9mm) at the mid-portion.

The 3D mapping showed an improvement of height greater than those calculated by the 9 points method.

Conclusions

The use of this permanent VCCEI in burst fractures allows quick discharge of patient and provides a good height restoration specifically for patients treated within one week after the traumatic event.

These preliminary results are encouraging and must lead to a further study enrolling a larger number of patients comparing this VCCEI with orthopedic treatments.

Moreover, the 3D mapping of the pre- and post-treated vertebrae might be a useful tool in the future to avoid measurements bias met with the 9 points method which does not show the complete vertebral body height restoration.

Preliminary experience on 37 patients treated percuatneously with a new vertebral cranio-caudal expandable implant in combination with cementoplasty after vertebral compression fractures.

Nicolas SANS

Radiological Society of North America / November 30th - December 5th, 2009. Chicago, USA

Purpose

The purpose of this study is to determine whether a new permanent vertebral cranio-caudal expandable implant (VCCEI) is able to reduce pain as well as to restore the anatomical shape of a fractured vertebra prior to its fixation.

Method and Material

37 patients (mean age: 53years old, 18F/19M) involving 40 traumatic VCF were prospectively enrolled in this clinical study. According to Magerl classification, there were 25 type A1 fractures, 11 type A2 and 4 type A3.1 fractures.

The mean time between the traumatic event and the surgery was 11 days.

All the patients underwent the procedure under general anesthesia and the two titanium expandable implants were positioned under fluoroscopic guidance through a transpedicular approach.

After implantation, the implants were open to reduce the fracture and cement injection was performed to stabilize the vertebral body in its reduced position.

The implant efficacy was assessed thanks to clinical criteria such as VAS score, pain medication and time to discharge. The ability of the VCCEI to restore the anatomy of the fractured vertebral body was based on a new method superimposing the 3D reconstructions of CTscans realized prior and after the surgery.

All data were collected and analyzed by an external statistical unit.

Results

No complication has been observed for any patient enrolled in the cohort. Mean time to discharge without brace was 2,2days. Pain was significantly reduced by 70% thanks to surgery (VAS score preop = 7, VAS score postop = 2) associated with pain medication reduction.

The CTscans analysis showed a general improvement of the vertebral body height (up to 10,6mm in the anterior part for a wedge fracture) and a reduction of the traumatic kyphosis vertebral angle (mean value: 26%, max value : 92%).

More interestingly, no significant change was observed at the posterior arch of the vertebral bodies.

Conclusion

The use of this new VCCEI in Vertebral Compression Fractures allows for a quick discharge and a good pain reduction. Those first results are encouraging as far as the anatomical restoration is concerned, and must lead to further comparative studies between this VCCEI with orthopedic treatments or vertebroplasty.

Clinical relevance/Application

The design of this VCCEI allows the radiologist to better control the anatomical fracture reduction because the expansion of the implant can be precisely controlled both in direction and height.

First clinical experience using a new intravertebral cranio-caudal expansion device allowing for vertebral anatomy restoration prior to its stabilization after Vertebral Compression Fracture (translated from German)

Joerg BEYERLEIN

German Spine Society (DWG) / December 10th - December 12th, 2009. Munich, Germany

Introduction

Literature exists on the importance of endplate reduction in Vertebral Compression Fractures (VCF) to avoid complications. Disc creeping, progressive kyphosis following disc collapse and compensatory hyperlordosis are some of symptoms following a non treated VCF. But, there is no evidence of anatomical fracture reduction when using current techniques of vertebroplasty or balloon kyphoplasty.

The purpose of this study is to assess the ability of a permanent intravertebral craniocaudal expandable implant to provide an anatomical restoration of the fractured vertebral body by reduction of the fractured endplates prior to its fixation using cement injection.

Material & Method

This new device consists in two expandable titanium implants that are placed under fluoroscopic guidance and through a percutaneous approach inside the vertebral body. They are deployed in a cranio-caudal way and are left inside while the cement is injected.

Within that frame, a post-market follow-up study has been set up to evaluate the ability of this new device to reduce the patient pain as well as to restore the anatomy of the vertebral body prior to its stabilization using cement injection.

25 patients (Mean age: 53 years old, 13F/12M) involving 28 VCF (22 single level and 3 double levels) were included in this study after a spinal traumatic event. According to Magerl classification, there were 18 A1, 6 A2 and 4 A3.1.

Mean fracture age was 10 days. Assessments of clinical and radiological parameters were performed prior to surgery, after surgery and 6 months postop.

Clinical parameters such as pain score (VAS), time to discharge, length of hospital stay were registered through this registry.

Radiographic parameters were collected using CT scans made prior to surgery (inclusion visit) and after treatment (discharge).

Post-treatment of CT scans data were performed by an independent external laboratory (LBM-ENSAM in PARIS). Each involved vertebra was accurately reconstructed for each evaluation step.

Then, a validated matching algorithm based on anatomical points on the posterior arch was used to superimpose the vertebrae and be able to compare them between the times of assessments.

Anatomical restoration was measured using a 3D mapping for each treated vertebra displaying the height change for each point belonging to the vertebra surface. Vertebral endplates angles changes were also monitored to assess the ability of the system to reduce the traumatic vertebral kyphosis angle.

Results

Time to discharge was 2,5 days on average and mean procedure duration was 47 minutes per vertebra.

No complication was reported (infection, adjacent fracture).

Over the 28 treated vertebrae, 13 asymptomatic minor leakages were reported either in the intervertebral disc or in the soft tissues.

This new intravertebral cranio-caudal expansion device is effective in pain reduction (VAS score decreased by 68,5% : from 7 preop to 2,2 postop) as well as in VCF reduction thanks to an anatomical restoration of the injured endplate as well as a traumatic kyphotic angle improvement up to 92%, and up to 10,8 mm height increase in the anterior part.

Neither antepulsion nor retropulsion of broken fragments were observed and displacements of the vertebral body posterior wall were negligible allowing surgeons to treat safely A3.1 fractures.

Discussion

This new reduction-reinforcement procedure has shown clinical and radiological efficacy in achieving anatomical reduction of VCF as well as reducing patients' pain. These first short-term results are currently being confirmed by longer-term follow-up assessment through this registry.

Prospective clinical and radiological evaluation of 37 patients after vertebral compression fractures (VCF) treatment.

David NORIEGA

Society for the Advancement of Spine Surgery- Asia Pacific / January 15th - January 17th, 2010. Hainan Island, China

Aims of study

The purpose of this study is to assess the ability of a new permanent vertebral craniocaudal expandable implant (VCCEI) to provide an anatomical restoration of the fractured vertebral body by reduction of the fractured endplates prior to its fixation using cement injection.

Method

A prospective international study enrolling 37 patients (Mean age: 53yo, 18F/19M) after a spinal traumatic event has been set up to evaluate the ability of the VCCEI to reduce pain as well as to restore the anatomy of the vertebral body. Mean fracture age was 11 days. Assessments of clinical and radiological parameters were performed prior to surgery, at discharge and 6 months postop. Heights restoration, and endplates' angles changes were obtained thanks to CT scans made prior to surgery (inclusion visit) and after treatment (discharge and 6 mo postop). CT scan data were analyzed by an external laboratory to build a 3D reconstruction of the involved vertebra for each evaluation step. Then, 3D reconstructions were superimposed using a validated matching algorithm based on anatomical points on the posterior arch to evaluate the study parameters. Pain scores were registered using VAS score at each step of the assessment schedule.

Results

The VCCEI achieves VCF reduction thanks to an anatomical restoration of the injured endplate as well as a kyphotic angle improvement up to 92%, and up to 10,8 mm height increase in the anterior part. Posterior wall displacements were negligible for all cases. Neither antepulsion nor retropulsion of broken fragments were observed.

Conclusion

The VCCEI procedure has shown clinical and radiological efficacy in achieving anatomical reduction of VCF as well as reducing patients' pain. Moreover its unique design allows the surgeon to apply controlled craniocaudal forces to reduce VCF without any ventral-dorsal forces preventing any bony fragment from being pulled out.

Optimal calendar to treat a vertebral compression fracture using a permanent intravertebral implant.

Aymeric DENIS

European Congress of Radiology / March 4th - March 8th, 2010. Vienna, Austria

Objective

Evaluate the influence of the fracture age on anatomical restoration when using a permanent intravertebral cranio-caudal expandable implant to treat vertebral compression fractures (VCF).

Material & Method

53 patients (29F/24M, mean age: 59yo) showing evidence of VCF were treated using 2 Titanium permanent cranio-caudal expandable implants in association with an acrylic cement. The procedures were performed through a transpedicular approach under general anesthesia and fluoroscopic guidance. For each patient, preoperative and postoperative CTScan were performed. From these millimetric CTscans, 3D reconstructions were obtained thanks to an innovative method developped by an independent laboratory. Then, the two 3D reconstructions were superimposed thanks to a matching algorithm based on the fact that the posterior arch was not affected by the procedure. This superimposition allows for a comprehensive assessment of the vertebral fracture reduction involving not only the cortical ring but also the endplates. Results were then analyzed considering three different groups which were defined according to the fracture age: group A –less than 10 days, group B – between 10 and 45 days and group C – more than 45 days of age.

Results

Restoration of the vertebral collapse was better in groups A and B than in group C (27% of mean reduction and 10% respectively).

Conclusion

VCF treatment results might be better if the reduction procedure is performed while the fracture is still mobile. Especially, the SpineJack® by pushing outward the broken endplates is able to give a global anatomical restoration of the vertebra.

A comprehensive method to perform and assess the results of anatomical restoration of Vertebral Compression Fractures.

Kieran MURPHY

Society of Interventional Radiology / March 13th - March 18th, 2010. Tampa, USA

Purpose

A prospective international multicentric study was setup to evaluate the ability of a new cranio-caudal expandable implant to restore the anatomy of vertebrae after Vertebral Compression Fractures (VCF).

Material and Method

37 patients (Mean age 53yo, 18 female, 19 male) were prospectively enrolled within this study after a VCF due to trauma (28 on normal and 12 on osteoporotic bone ; 9 biconcave, 20 wedge and 11 crush). According to Magerl classification, there were 25 A1, 11 A2 and 4 A3.1. fractures. Patients underwent the treatment 11 days after fracture on average. The procedure has consisted in putting two permanent titanium implants through bilateral transpedicular approach in their close position. Then, the implants were expanded in a fully controlled way to apply forces on the broken parts of the vertebra and reduce the fracture and let in place until acrylic cement injection to stabilize the reduction. To assess the anatomical restoration, a specific method was developed in collaboration with a biomechanics lab. Based on millimetric computer tomography (CT) scanner slices, the method allows superimposing two 3D reconstructions to evaluate the anatomical restoration obtained thanks to the procedure. Thus, vertebral kyphosis and vertebral endplates reduction were assessed. Any cement leakages were also reported using CTscan.

Results

Neither major complications nor adverse event were reported for any of the procedures but asymptomatic cement leakages (50%). Anatomical reduction of the fractured vertebrae was achieved both for vertebral kyphosis and endplates reduction. Vertebral kyphosis was reduced up to 92% and by 30%, 21%, 28% on average for wedge, biconcave and crush fractures respectively. Endplates reduction was also obtained (up to 10,9mm in the anterior part) and the new superimposition method has allowed highlighting the ability of this new procedure to restore the cortical ring as well as the endplates. Interestingly, the control provided by this technique enabled to treat A3.1 fractures without causing any retro- or ante-pulsion of broken fragments while reducing the fracture.

Conclusion

Using this new 3D assessment method based on CTscan, anatomical restoration of the fractured vertebra involving cortical ring as well as endplate reduction could be precisely quantified without the bias due to conventional X-rays assessment methods. Especially, it was possible to assess the correction obtained on the broken endplates while detecting all the possible cement leakages.

Clinical and radiological results when treating Vertebral Compression Fractures (VCF) with a new cranio-caudal expandable implant: Prospective study on 38 traumatic cases.

David NORIEGA

Spine Arthroplasty Society / April 27th - April 30th, 2010. New Orleans, USA

Purpose

This study aims at determining whether a new procedure involving a cranio-caudal expandable intravertebral implant and cement stabilization is able to provide good clinical and radiological results for VCF treatment.

Method

38 patients with significant pain due to traumatic VCF (52,5yo on average, 20 male and 18 female) were prospectively enrolled in this study. Fifty percent of the female patients had known osteoporotic bone condition) In total, 42 VCF were treated according to this new procedure 3,6days after the traumatic event (1xT10, 1xT11, 6xT12, 16xL1, 11xL2, 4xL3, 3xL4). According to Magerl classification, there were 25xtype A1, 7xtype A2 and 10x typeA3.1 vertebral fractures. The procedure consisted in placing two Titanium cranio-caudal expandable implants through bilateral transpedicular approach under fluoroscopic guidance and to optimally position them with respect to the fractured area of the vertebral body. Then, they were expanded until the fracture of the vertebral body was reduced and let in place while final stabilization was obtained by acrylic cement injection using the same surgical approach. Assessment of the technique was made using VAS score and a new method based on 3D CTScans reconstructions superimposition developed in collaboration with a biomechanics laboratory in Paris (ENSAM-LBM).

Findings

Neither perioperative nor postoperative complications occurred. Minor asymptomatic cement leakages were reported in 45% of the treated vertebrae. On average, 5.9 mL of acrylic cement were injected in each treated vertebra (3.1 via the right pedicle and 2.8 via the left pedicle). Patients were discharged three days after the procedure on average without any postoperative bracing. Mean follow-up was 9.8 months. Pain assessment has demonstrated an effective and sustainable pain relief with 71.8%, 81.6% and 90.1% of pain reduction at discharge, at 6month follow-up and one year postop respectively. The 3D assessment method demonstrated a significant vertebral body volume increase of 7% on average. Similarly, heights of the vertebral body were increased by 11% (up to 10mm of defect correction), 13% (up to 11mm of defect correction) and 0% in the anterior, medial and posterior parts of the vertebral body respectively. More interestingly, this new method allowed quantification of the defects correction noticeable in the vertebral endplates prior to surgery. Lastly, vertebral kyphosis was significantly reduced by 46% (from 9.65° at preop to 5.24° at discharge).

Conclusions

Our results show for the first time that with an intravertebral cranio-caudal expandable implant we are able to restore height and achieve anatomical restoration in traumatic VCF. This method seems to be superior to conventional treatments because of its direct impact on the endplates. Further studies need to confirm the long-term benefits.

Is anatomical restoration in Vertebral Compression Fracture (VCF) treatment achievable?

David NORIEGA

South African Spine Society / May 19th - May 22nd, 2010. Capetown, South Africa

Purpose/aim of study

This work aims to determine whether anatomical restoration of a vertebral body after VCF can be achieved and what may be the additional advantages of such a reduction.

Method

More than 140 patients were enrolled in a prospective European multicenter registry. They all underwent a new percutaneous minimal invasive procedure combining the use of permanent intravertebral cranio-caudal expandable implants with acrylic cement injection. Clinical assessment was realized using CRF to monitor pain (VAS score) as well as procedure details and possible adverse event. Anatomical restoration was assessed comparing accurate 3D reconstructions based on CTScan images.

Results

Over the 144 procedures, no major complication has occurred. For the 41 patients with a minimum 6month follow-up, VAS score showed an immediate and sustained pain relief (7,04preop/1,84discharge/1,286month/1,0812month). Mean time to discharge was 2,7days after the surgery. Average volume of cement injected per vertebra was 5,92mL. Adjacent fractures occurred in only 4,3% of the cases. Vertebral body volumes were increased by 8% on average (up to 33%) and broken endplates were pushed outwards as well as vertebral angles were reduced (up to 10,8mm and 9,9mm of height restoration in the anterior and medial planes while the posterior wall remains unchanged and up to 16° of vertebral angle correction).

Conclusion

Those results are demonstrating that the anatomical reduction in VCF treatment is feasible and efficient for pain relief using this new procedure. Greater cohort analysis at 6month follow-up may show that this new technique involving endplates reduction may be of interest as far as the adjacent fracture occurrence rate is concerned.

What should be an anatomical reduction considering traumatic vertebral compression fractures?

Nils HANSEN-ALGENSTAEDT

Federation of European Associations of Orthopaedics and Traumatology / June 2nd - June 5th, 2010. Madrid, Spain

Introduction

It is commonly admitted that for any joint fracture in the human body, a perfect anatomical reduction before stabilization is the only manner to biomechanically restore a joint and avoid late complications by early mobilization allowance. But, there is no evidence of anatomical fracture reduction when using vertebroplasty or balloon kyphoplasty in case of traumatic vertebral compression fractures (VCF).

Material & Method

A new procedure was proposed using titanium permanent vertebral cranio-caudal expandable implants (VCCEI) in combination with PMMA cementoplasty. The procedure has consisted in two steps: first, reduce the fractured vertebral body under fluoroscopic guidance by expanding the implants and second, stabilize the vertebra in its reduced position using PMMA cement injection. The implants ability to reduce the fractured endplates was assessed within a prospective international clinical study enrolling 37 patients (Mean age: 53yo, 18F/19M). 40 VCF (34 single level and 3 double levels) were included in this series. Mean fracture age was 11 days at the time of surgery. To evaluate the anatomical restoration, a new 3D measurement method was developed using millimetric CT scans 3D reconstructions. Morphologic parameters such as vertebral kyphosis angle and endplate surface restoration were calculated and clinical parameters were monitored (VAS score monitoring, hospital stay duration).

Results

First results are showing that the VCCEI is able to reduce the fractured vertebra whatever is the type of fracture providing that it is still mobile. Both vertebral kyphosis angle reduction and endplate surface restoration were achieved: up to 92% improvement for vertebral kyphosis and up to 10,8mm height increase in the anterior part of a fractured endplate. Posterior wall displacements were negligible. Neither antepulsion nor retropulsion of broken fragments were observed. No postoperative complication was reported but minor asymptomatic cement leakages. Pain was significantly reduced at the same time and hospital stay was comparable to vertebroplasty.

Conclusion

This new procedure has demonstrated its clinical and radiological efficacy in achieving anatomical reduction of VCF as well as relieving pain. The unique design of this VCCEI allows the surgeon to apply controlled cranio-caudal forces to reduce the fractured vertebra according to the fracture type and thus optimize the way the fracture will be reduced. Providing that the technique allows for a good control of the way the reduction is performed, there is a new possibility to treat VCF as they should deserve.

A comprehensive method to perform and assess the results of anatomical restoration of VCF

David NORIEGA

International Meeting on Advanced Spine Technologies / July 21st - July 24th, 2010. Toronto, Canada

Purpose

A prospective international multicentric study was setup to evaluate the ability of a new cranio-caudal expandable implant to restore the anatomy of vertebrae after Vertebral Compression Fractures (VCF).

Material and Method

37 patients (Mean age 53yo, 18 female, 19 male) were prospectively enrolled within this study after a VCF due to trauma (28 on normal and 12 on osteoporotic bone ; 9 biconcave, 20 wedge and 11 crush). According to Magerl classification, there were 25 A1, 11 A2 and 4 A3.1 fractures. Patients underwent the treatment 11 days after fracture on average. The procedure has consisted in putting two permanent titanium implants through bilateral transpedicular approach in their close position. Then, the implants were expanded in a fully controlled way to apply forces on the broken parts of the vertebra and reduce the fracture and let in place until acrylic cement injection to stabilize the reduction. To assess the anatomical restoration, a specific method was developed in collaboration with a biomechanics lab. Based on millimetric computer tomography (CT) scanner slices, the method allows superimposing two 3D reconstructions to evaluate the anatomical restoration obtained thanks to the procedure. Thus, vertebral kyphosis and vertebral endplates reduction were assessed. Any cement leakages were also reported using CTscan.

Results

Neither major complications nor adverse event were reported for any of the procedures but asymptomatic cement leakages (50%). Anatomical reduction of the fractured vertebrae was achieved both for vertebral kyphosis and endplates reduction. Vertebral kyphosis was reduced up to 92% and by 30%, 21%, 28% on average for wedge, biconcave and crush fractures respectively. Endplates reduction was also obtained (up to 10,9mm in the anterior part) and the new superimposition method has allowed highlighting the ability of this new procedure to restore the cortical ring as well as the endplates. Interestingly, the control provided by this technique enabled to treat A3.1 fractures without causing any retro- or ante-pulsion of broken fragments while reducing the fracture.

Conclusion

Using this new 3D assessment method based on CTscan, anatomical restoration of the fractured vertebra involving cortical ring as well as endplate reduction could be precisely quantified without the bias due to conventional X-rays assessment methods. Especially, it was possible to assess the correction obtained on the broken endplates while detecting all the possible cement leakages.

Endplate anatomical restoration may reduce adjacent fracture occurrence when using a new cranio-caudal expandable implant for Vertebral Compression Fracture treatment.

David NORIEGA

EUROSPINE / September 15th - September 17th, 2010. Vienna, Austria

Background Context

Literature about subsequent adjacent vertebral fractures occurring after VCF treatment has shown that there are fewer subsequent fractures when using balloon kyphoplasty than with non-surgical care. In the same time, a recent biomechanical study has demonstrated the role that can play the endplate deformity on the disc pressure profile load sharing and then on the adjacent fracture occurrence.

Purpose

The purpose of this study is therefore to analyze the occurrence rate of subsequent adjacent vertebral fractures when using a new vertebral cranio-caudal expandable implant (VCCEI) in combination with PMMA cement injection.

Study Design

A prospective observational study enrolling 134 patients has been designed to evaluate the ability of the VCCEI to restore the anatomy of the fractured vertebrae and to limit the occurrence of adjacent ractures.

Patient Sample

Mean fracture age was 32,4 days at the time of surgery. Assessments of clinical and radiological parameters were performed prior to surgery, after surgery, 6 months postop [30 patients – 34 VCF] and 12 month postop [14 patients – 16 VCF].

Outcome Measures

Using CTscans images, heights restoration, endplates' angles changes were obtained for each scheduled visit [preop/exit/6m/12m]. Any subsequent fracture was registered within the follow-up period using XRay and CTscan exams.

Method

CT scan data were analyzed by an independent laboratory (LBM, ENSAM – PARIS) to build a 3D reconstruction of the involved vertebra for each evaluation step. Then, 3D reconstructions were superimposed using a validated matching algorithm based on anatomical points on the posterior arch to evaluate the study parameters.

Results

The VCCEI allows achieving VCF reduction thanks to an anatomical restoration of the injured endplate as well as a kyphotic angle improvement up to 92%, and up to 10,8 mm height increase in the anterior part. More interestingly only 2 subsequent fractures were reported at 6 month (none at 12month) over 34VCF corresponding to a lower rate of adjacent fractures when compared to balloon kyphoplasty and non surgical care.

Conclusion

While providing an anatomical restoration of the vertebral body including the vertebral endplates, this new procedure could be of interest when looking at the adjacent fracture occurrence rate in the mid and long-term results.

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