# American Journal & Osteopathic Neurological Surgery

2010 VO

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## EDITOR'S PAGE

Physicians in training, learn and practice research "To formulate, ingrain, and measure, a method of thought, investigation, and evaluation necessary for physicians to have multi-lateral information exchange and communication with experts in areas of scientific and medical discovery, knowledge, and analysis, in order to continuously and efficiently improve human health and patient care." Understanding and performing quality research provides students and residents the tools to propel quality medical care into the community and into the future.

Welcome to the quarterly American Journal of Osteopathic Neurological Surgery and the American College of Osteopathic Surgeons Neurosurgical Discipline. This volume is composed of selected papers that were submitted but not published elsewhere. It is therefore dedicated to the future Neurosurgeons and their education. All papers were reviewed by the peer review committee and selected for publication. The papers submitted are excellent, representing some of our talented colleagues. Issues will be published quarterly. I hope that this issue will spread the knowledge of our residents and our section. We will continue to solicit annual papers and all papers submitted at the annual meeting. This is your Journal paid for by your annual dues. This issue is available on our website AOANeurosurgery.org. This is your organization; please support it as you can.

Thank you,

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# Kyphoplasty Patient-centered Outcomes via Questionnaire

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Disclosures and Funding: None

# Abstract/Keywords

**Aim/Background:** To assess patient centered outcomes among adults with compression fractures treated by kyphoplasty.

**Methods:** A 3-question survey was administered via telephone to patients who had a kyphoplasty procedure performed from 2008-2011.

**Results:** One hundred fifty one patients completed the telephone satisfaction survey. Of these, 95.4% of respondents said the procedure was tolerable, 82.8% had full or partial pain relief and 66.2% would have the procedure again.

**Conclusions:** Large randomized and observational evidence support the use of kyphoplasty in osteoporotic and malignant compression fractures. Based on our survey, patients believe kyphoplasty is a tolerable procedure that produces full or partial pain relief and would undergo the procedure again if needed.

Key Words: kyphoplasty, vertebroplasty, compression fracture, patient satisfaction

# Introduction

Cement augmentation of vertebral bodies began in 1987 with the treatment of vertebral hemangiomas by Gailbert et al<sup>1</sup>. In 2001, kyphoplasty was introduced as a novel method of augmenting vertebral bodies with cement<sup>2</sup>. In 2009, two studies of vertebroplasty versus sham

procedure concluded that vertebroplasty was unsuccessful<sup>3,4</sup>. Kyphoplasty usage declined significantly in 2009, presumably secondary to the results published in these two studies<sup>5</sup>. Despite these reported outcomes, anecdotal success with kyphoplasty continued among individual surgeons. Other publications subsequently appeared in the literature that directly contradicted the results from the sham studies, including one randomized controlled trial<sup>6</sup> and one large observational study<sup>7</sup>. Results from these studies have highlighted kyphoplastys' ability to decrease subjective measures such as back pain<sup>6,7,8,9</sup>, improve quality of life<sup>6,9</sup>, reduce physical disability and decrease mortality<sup>10,11,12</sup>. The effect has been studied mainly in the osteoporosis literature but has also shown effectiveness in the groups of patients suffering from pathological fracture secondary to malignancy<sup>13</sup>. The economic impact of kyphoplasty has been studied and shown to reduce healthcare utilization<sup>14</sup>, shorten hospital stay<sup>10, 11</sup> decrease outpatient follow up visits<sup>15</sup>, and reduce narcotic use<sup>7</sup>.Currently, healthcare reimbursement is dependent upon not only standardized measures of success but also high patient satisfaction. Current research supports the use of kyphoplasty from a functional and economic standpoint but looking at patients' perspective in medical research is important to complete the overall picture of efficacy. To date in the kyphoplasty literature, only one paper, the 2-year follow up from the FREE paper, has mentioned patient satisfaction using a 20-point Likert scale<sup>9</sup>. They mention statistical significance but do not elaborate on the subject. The objective of our survey was to assess patient-centered outcome measures using specific questions directed at procedure tolerability, pain relief, and willingness to undergo the same procedure again to show the benefits of kyphoplasty not only objectively, but also subjectively from the patients' perspective.

# **Materials and Methods**

## Patients

Patients were included in this study if they were >18 years old, with an acute compression fracture confirmed by MRI or nuclear bone scan, and had a kyphoplasty performed. Patients were identified using a coding query from clinic and hospital electronic medical record. All patients who had undergone a kyphoplasty procedure from 2008-2011 were identified. Demographic data from these patients were obtained through electronic medical records. The social security numbers of the patients were checked against the Social Security Death Index (<u>http://www.genealogybank.com/gbnk/ssdi/</u>). The deceased patients were identified and excluded from the study. The indication for kyphoplasty was assessed using the medical records as well as pathological information from bone biopsy. They were separated into osteoporotic/spontaneous fractures, fractures related to biopsy-proven malignancy, or traumatic fractures.

# Kyphoplasty

Patients were eligible for kyphoplasty based on Magnetic Resonance Imaging or Nuclear Bone Scan demonstrating an acute compression fracture, hyperintensity on STIR sequences and hypointensity on T1 sequencess suggesting edema, as well as clinical findings of intractable back pain despite non-operative treatment. All patients identified had a kyphoplasty performed by unipedicular, bipedicular or extrapedicular approach depending upon surgeon preference. All kyphoplasty was performed using the Kyphon Balloon Kyphoplasty system (Medtronic Spine, LLC, Sunnyvale, CA,USA).

# Survey

The included patients were contacted through telephone numbers obtained in the demographic data of their electronic health record. The "Kyphoplasty Telephone Satisfaction Survey", a simple three-question survey, was administered to the patient. Institutional review board approval was obtained prior to data collection. Each question is available in Figures 2, 3 and 4. No family member was allowed to take the survey for the patient. If the patient was unable to complete the interview through the telephone they were excluded from the survey and study. If the patient was unavailable for conversation or unreachable, two more attempts were made, for a total of three attempts, before the patient was counted as unreachable and excluded.

# Results

Four hundred ninety two patients were identified from the coding query. Of these, 173 patients were excluded due to identification on the Social Security Death Index as being deceased. Three hundred nineteen patients remained. Nine patients refused to participate in the questionnaire and were excluded. One hundred and fifty nine were unreachable or unable to complete the questionnaire. The remaining 151 of available 310 alive participants were reached and completed the survey, a response rate of 48.7%.

This patient cohort of respondents represents a typical variety for a private practice physician performing these procedures. Full characteristics of the respondents are presented in table 1. The majority of the patients were Caucasian females. The age range was from 26-101, with an average age of 74.3. The most common level requiring kyphoplasty was L1, followed by T12 and then L2. Overall, 61.3% of fractures were at the thoracolumbar junction (T10-L2). Most patients (130 of 151) had either one or two levels treated. No patient had more than three levels performed at one time. The cause for surgery was mainly osteoporotic or spontaneous fractures, which accounted for 72.0% of all patients.

Overall, 95.4% of respondents said the procedure was tolerable. When asked regarding pain relief, 82.8% of respondents had partial or full pain relief from the procedure, with 55.0%

overall stating "yes" to the pain relief question. When asked whether they would have the procedure again, 66.2% of respondents stated "yes". Full survey results are listed in table 2.

# Discussion

This simple questionnaire study showed, from the patient perspective, that treating compression fractures by balloon kyphoplasty is a tolerable procedure that results in subjective pain relief. Based on our findings, most patients' perspective on kyphoplasty is that given another compression fracture, they would opt for re-operation in the form of kyphoplasty.

Since the two studies in 2009 that showed no benefit of vertebroplasty over sham surgery, there have been large studies specifically regarding kyphoplasty which have contradicted this finding. While there have been many smaller non-randomized studies<sup>8,14</sup>, two major studies<sup>6,7</sup> and a systematic reviews<sup>16</sup> have shown objective decrease in pain, improvement of quality of life and decrease in physical disability from kyphoplasty as compared to conservative management<sup>6,7</sup>.

The patient population presented is similar to the only previous large kyphoplasty specific studies. The FREE trial had 149 patients in their kyphoplasty group of which 77% were female, the SWISS observational study 69.6% female, whereas our study contained 81% female. The average age of our patients was 74.0 while FREE had an average age of 72.2 and the SWISS study, 69.4.

Overall, 58.3% of patients had one fracture treated, compared with 67% for FREE and 77.1% for the SWISS study. The number of patients with two fractures treated was higher in our population at 27.8% than previously mentioned studies. Differences in these numbers may exist as many of our patients had more than one surgery within our four-year collection period, while the FREE study had only one surgical intervention, while it is not clear in the SWISS study if patients were treated in multiple surgeries. Most of the fractures treated were in a similar area to previous studies; 61.3% were treated at the thoracolumbar junction (T10-L2) in our respondents as compared to 59% in the FREE trial.

Our stratification of patients was similar to the stratification in the SWISS study. Spontaneous fracture was noted in 72.2% of our patients. Osteoporosis was noted in 83.5% of SWISS patients. Trauma was the cause in 14.6% of our patients, while the SWISS study had 12.2%. Finally cancer or pathologic fracture was the cause of 7.3% of our patients and 4.3% of SWISS patients.

The FREE study also collected patient satisfaction data based on a 20 point Likert scale and noted statistical significance to from 1 month to 24 months post operatively. The data presented here show similar results and attempt to build on the FREE results. The questionnaire used in this study was aimed at gathering additional and more specific patient-centered outcomes on kyphoplasty.

Our questionnaire is subject to recall bias. The patients who had procedures in 2008 were called in 2013, thereby introducing approximately 5 years between time of procedure and questionnaire administration. When breaking down the data to compare years, patients who had the procedure in 2008 had the same overall trend in answer choice, with one exception. Patients in 2008 responded "somewhat" to pain relief question 2 53.8%, and "yes" only 28.6% of the time. This trend was reversed in all following years. This finding could be a result of improved surgeon skill over time or recall bias as described above. A perceived limitation of this study may be the lack of objective data such as ODI, RM scale, VAS scale, but we were only attempting to elicit the patients' individual perspective using patient-centered outcome data.

# Conclusion

Since kyphoplasty's inception, a rocky road has lead from individual anecdotal success to large randomized and observational evidence supporting its use in selected populations. In a changing healthcare environment, it is paramount that patient satisfaction is high among selected procedures. Our population of patients has now shown that kyphoplasty is also well-tolerated, effective, and desirable, based on individual patient perspective.

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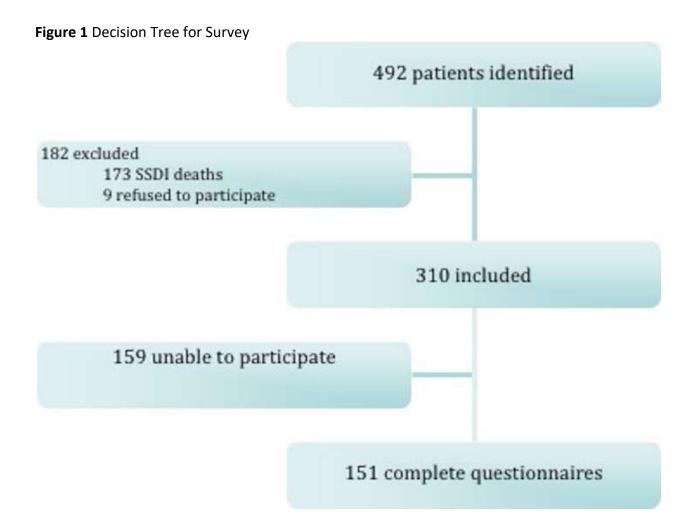
# TABLE 1

Table 1 - Patient Characteristics	
Sex	
Male	29
Female	122
Race	
Caucasian	101
African American	12
Asian	1
Unreported	37
Age	
<50	5
50-69	42
70-89	98
>90	6
Cause of Fracture	
Spontaneous/Osteoporotic	109
Malignancy	11
Trauma	22
Unknown	9
Number of Levels	
1	88
2	42
3	12
4	4
5	2
6	0
7	2
8	0
9	1
Levels	
T2	1

Т3	3
T4	4
T5	3
Т6	6
Т7	12
Т8	13
Т9	10
T10	8
T11	23
T12	40
L1	50
L2	38
L3	19
L4	15
L5	14

# TABLE 2

Table 2 - Questionnaire Results							
Q1. Was the procedure to inject cement into your fracture tolerable?							
Yes 144							
No	7						
Q2. Was the pain in your back relieve	ed by the procedure to inject						
cement into your fracture?							
Yes 83							
Somewhat	42						
No	26						
Q3. Would you have the same procee	dure again?						
Yes	100						
Not Sure 27							
No	24						



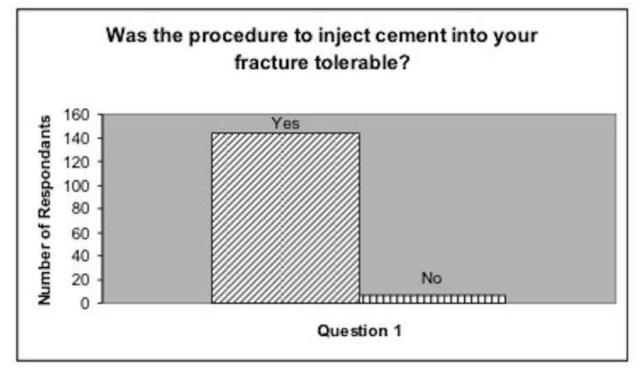


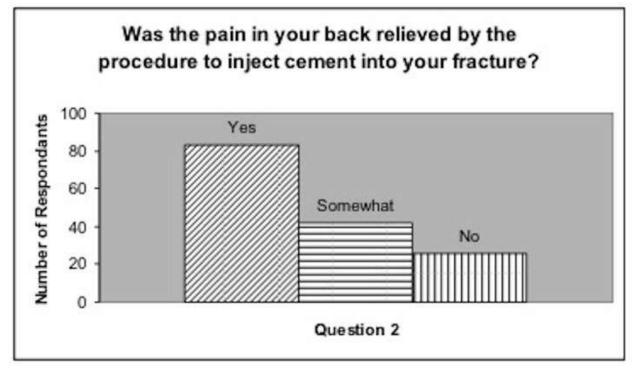
Figure 2 Question 1 of telephone questionnaire.

⊠ Yes

□Somewhat

□ No





Ø Yes

■Not Sure

□ No

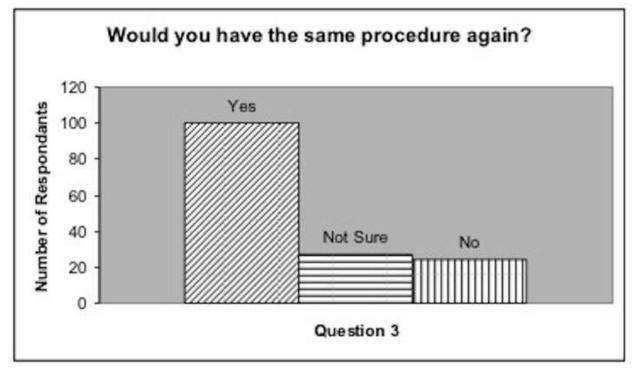


Figure 4 Question 3 of telephone questionnaire.

⊠ Yes

■Not Sure

□ No

## Use of the Acutrak 4/5 Headless Fully Threaded Variable Pitch Compression Screw for Odontoid Fixation in Type II Odontoid Fractures: A Technical note and Case Series compared with the standard Technique in a Single Institution

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## Abstract:

**Study design**: Retrospective review of patients treated at a Level One Trauma Center for acute type II odontoid fracture using 2 different types of odontoid screws. Group A patients were treated with a standard lag screw and Group B patients were treated using an Acutrak 4/5 headless compression screw.

**Objective**: To evaluate the clinical and radiographic results of patients treated with an Acutrak 4/5 headless compression screw for acute type II odontoid fracture, and to demonstrate non-inferiority compared to standard technique.

**Background**: Type II odontoid fracture is a common cervical spine fracture that disproportionately afflicts the elderly. An anterior odontoid screw allows immediate fixation, preserves C1/2 motion, and is highly effective in fracture healing of acute fractures in patients with anatomically favorable fracture morphology and body habitus. The traditional approach uses a lag technique that can be technically challenging and invariably disrupts the C2/3 disk to some degree. The Acutrak 4/5 is a headless fully threaded variable pitch compression screw that has been described once in the literature to successfully treat an odontoid fracture. This is the largest case series on the use of this novel technique. This technique is simpler and allows for a steeper angle of approach, easier reduction, and can help minimize C2/3 disk disruption.

**Methods**: We retrospectively analyzed 44 patients between 2002 and 2014 who underwent an anterior odontoid fixation with either or a traditional lag screw (group A) or Acutrak 4/5 screw (group B) for stabilization of type II odontoid fractures, and report results of 30 patients with follow up data.

#### Result:

We identified 14 patients who were treated using the lag screw technique and 16 patients using the Acutrak technique with follow up data. The mean radiographic follow up was 5.1 month and 3.1 month for the lag technique and Acutrak technique, respectively (p=0.082). The mean clinical follow up was 6.6 months and 4.9 months, respectively, for Groups A and B, respectively (p=0.467). The average age of patients who received the lag screw was 68, and Acutrak screw 79 (p=0.1). Overall the fusion/stable fibrous union rate of Acutrak technique was 68% while for the lag technique was 78% (p=0.337). Excluding two patients that we learned in retrospect were not good candidate for anterior approach yield as adjust rate of 75% for the Acutrak group (P=0.887).

#### Conclusion

Odontoid screw fixation for acute type II odontoid fractures provides an acceptable rate of fracture healing and preserved C1/2 motion. The use of a headless fully threaded variable pitch compression screw such as the Acutrak 4/5 is technically easier and provides an equivalent outcome comparable to the conventional lag screw. Long term follow up with a larger patient cohort would be needed to assess the durability of this technique.

## Introduction

Odontoid fractures are common entities in the geriatric population. Fractures of the odontoid account for approximately 20% of all cervical fractures, and approximately 70% of these are type II fractures<sup>1</sup>. It involves a fracture through the base of the dens without involvement of the body. These are unstable fractures and treatment options are controversial as there are currently no standards of treatment or guidelines. Several risk factors have been associated with an increase likelihood that conservative treatment options may fail to achieve a stable fusion . Age > 50 has been associated with an 21 fold risk of increased non-union rate<sup>2</sup>. A fracture gap of > 2mm, odontoid displacement > 5 mm or the inability to obtain acceptable reduction and fracture alignment with a halo or collar are all associated with a high risk of bony non-union and may be indications for surgical fixation<sup>3</sup>.

Two basic surgical approaches for fixation of odontoid fractures include the anterior odontoid screw fixation and posterior cervical atlantoaxial fusion techniques. The optimal surgical approach depends on both clinical and radiographic factors. The anterior approach using an odontoid screw is an attractive option because of benefits such as direct osteosynthesis, preservation of C1/2 motion, and fusion rates ranging from 75 to 100 in all age group. <sup>4,5</sup>. However, in the elderly, there is a high rate of failure of initial treatment<sup>6</sup> and the rate of nonunion in odontoid fixation has been reported as high as 75%<sup>7</sup>. Anterior odontoid fixation can be a technically challenging procedure but is a favored approach in patients with a fracture line in the anterosuperior to posteroinferior orientation with an intact transverse ligament, fractures < 6 months old and in patients without severe cervicothoracic kyphosis, osteoporosis or inappropriate body habitus (i.e. barrel chest).



Figure 1 Acutrak 4/5 headless compression screw

There is variability in the anterior odontoid screw fixation technique. Most surgeons use a partially threaded lag screw or a fully thread threw via a lag technique, where the proximal part of C2 is overdrilled, making a glide hole to reduce and stabilize the fracture. There are also cannulated systems using a K wire. The Acutrak 4/5 is a headless, fully-threaded, self tapping, cannulated, tapered screw with variable pitch designed to provide sufficient compressive force across fracture line with insertion (Figure 1). This type of screw is commonly used by orthopedic surgeons for the reduction of scaphoid fractures. In our institution, we use the lag screw for odontoid fixation and since 2009, the senior author (SY) and colleagues have been using a modified technique for odontoid fixation using the Acutrak 4/5 to treat selected patients with acute type II odontoid fractures with good results. There is only one previous case report published in 2013 describing the use of this screw for anterior odontoid fixation<sup>8</sup>. The purpose of this report is to critically analyze both clinical and radiographic outcomes of a series of patients treat with the Acutrak 4/5 screw in anterior odontoid fixation for Type II odontoid fractures compared to our own cohort of patients using the standard lag screw.

## Methods

We retrospectively reviewed data from 44 consecutive patients who were operated on in the Department of Neurosurgery at a regional level 1 Trauma center between the 2002 and 2014 using anterior odontoid screw fixation for traumatic type II odontoid fractures. The study was approved by the Cooper University Hospital IRB. Inclusion criteria include patients with traumatic odontoid fractures with pre and postoperative imaging and clinical follow up data. Pathologic fractures were excluded. Study parameters include age, gender, complications, surgeon, length of radiographic and clinical follow up, timing of surgery (immediate= within 3 days of injury). Management of patients was determined by the treating surgeon as to whether conservative therapy was offered first versus odontoid fixation. Follow up data was obtained from clinic notes and/or radiographic data. Assessment of good outcome was assessed clinically and/or radiographically. Good result included freedom from pain and neurological symptoms with full range of movement in all direction, lack of abnormal motion on postoperative flexion extension x-rays, or evidence of bony fusion. Poor result includes requirement of revision surgery, refractory pain, clinical myelopathy, and/or demonstrated unstable nonunion on flexion extension x-rays.

# **Surgical procedure**

In brief, all patients were consented for surgery with benefits, risks , and alternatives fully explained. The operation was done in a supine position. General anesthesia was administered. The surgical technique for the exposure is the same for both techniques. A transverse incision along a fold in the neck just medial to the border of the sternocleidomastoid was made. Using Metzenbaum scissors, the skin was undermined. Prevertebral space was exposed using sharp dissection and carried up just to the bottom of C2.

For the standard technique with the lag screw, 2 C-arm were positioned to provide intra-operative fluoroscopic images in opened mouth AP and lateral views centered at C2. A trough was made at the C2/3 disk space with an small annulotomy. An awl was used to make a starting point at the inferior anterior corner of C2. This was then drilled with 2.5mm bit through the distal tip of the fractured fragment for a pilot hole. Then a 3.5mm tap was used to broach nearly the length the C2 fragment followed by a 3.5 to 4.0mm partially threaded lag screwed until it was fully engaged in the fragment with reduction on x-ray. The length of the screw was carefully calculated so that the threads will be distal to fracture line when the screwed is fully tightened in the fragment. The wound is inspected for bleeding and closed in standard fashion.

For the Acutrak technique, except for 3 cases done before 2009, the AP and lateral fluoroscopy was replaced by the O-Arm. After manual reduction prior to fixation, a scan was done to ensure adequate alignment and reduction. The procedure is essentially the same except there is minimal to no C2/3 annulotomy. There was no need to premeasure of

the length of screw to ensure the thread will be distal to the fracture line. Typically, a 30mm to 35mm screw was used to span the length of the C2. The pilot hole is drilled using a generic 3.2mm bit drill. We do not use a guidewire or the standard Acutrak cannulated drill. Following the tap of only 1-2cm of proximal C2, a 4/5 Acutrak screw is tightened into the fracture fragment until satisfactory reduction as it slightly countersinks into the body of C2. To help overcome the shallow angle needed in patients with large chest, we use a customize-made flexible hex screw driver. An intraoperative O-arm spin was then done to verify accuracy of screw placement. If satisfactory, the wound is then closed. The patient is

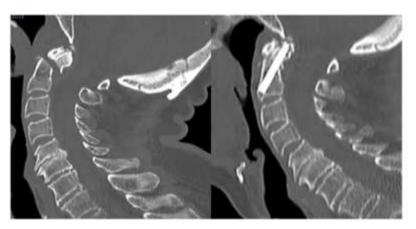


Figure 2 example of a well placed Acutrak screw. Note the proximal aspect of the screw does not disrupt the C2/3 disk space.

placed in a rigid C-collar. Usually, A CT cervical spine was done by postop day 1.

# Statistical analysis

The following information was extracted from the medical record: preoperative neurologic status, surgical complications, symptoms and neurological status at the time of the most recent follow-up along with imaging studies. The patient returned to the outpatient office at 2, 6 and 12

weeks, sometimes 6 months and 12 month post-op depending on the treating surgeon.

Statistical analysis was done by comparing two groups: group A being the lag screw technique cases, and Group B the Acutrak technique cases. The T test was used to compare average age as well as average length of follow up between the lag screw and the Acutrak screw technique cases. Statistical analysis was done comparing results of the surgery, this was done using the Chi Squared test. Univariable analysis was done to test effect of gender, treating surgeon, age at time of operation above or less than 70, timing of surgery (delayed surgery greater 6 week post injury versus early surgery), all using the Chi Squared test.

# **Radiographic interpretation:**

Image data was interpreted by the surgeon, the lead author (XX), and the reading radiologist. In cases where radiographic imaging were not available, the data was obtained by official read and/or surgeon's interpretation from clinic notes.

# Results

# **Patient demographics**

We identified 44 patients that underwent an anterior odontoid fixation for traumatic unstable odontoid fractures at our institution between 2002 and 2014. There were 22 cased that was identified as using the lag screw technique, 19 cases using the Acutrak screw technique, and three patients there were no data on which screw was used. We found follow-up data on 30 cases. 16 cases were Acutrak cases, 14 were lag screw case.

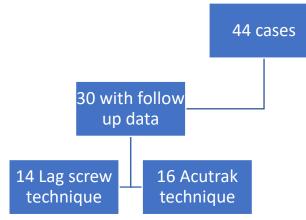


Figure 3 chart search

The average age of patients who received the lag screw was 68, and Acutrak screw 79 with p value of 0.1. The range of age was from19 to 90. The mean radiographic follow up was 5.1 month and 3.1 month for the lag technique and Acutrak techniques, respectively (p=0.082). The mean clinical follow up was 6.6 month and 4.9month, respectively (p=0.467). There was also no significant difference in gender between

the two groups (p=0.23). There were a total of 6 different neurosurgeons who

operated on these 30 patients. However, all but 4 cases were operated on by two senior surgeons, SY and AT. There was no significant difference between the two group in terms who the surgeon was. Lastly, there was no significant difference between the two group in terms of timing of surgery from initial injury. All but two patients were neurologically intact. Patient 19 presented with spinal cord injury. Patient 24 had concomitant severe TBI. Patient 30 was neurologically intact but had a delayed failure of surgery with loss of reduction and symptomatic instability. He required a posterior C1-2 fusion and did well

	Group A:Lag	Group B:	р
	screw	Acutrak screw	value
average age	68	79	0.1
mean radiographic			0.082
follow up	5.1 m	3.1 m	
mean clinical	6.6 m	4.9 m	0.467
			I
female	10 (71%)	8 (50%)	
male	4 (29%)	8 (50%)	0.23
surgeon: SY	9 (75%)	13 (81%)	
surgeon: AT	3(25%)	2 (12.5%)	0.432
delayed surgery	1 (7%)	3 (18.8%)	
immediate surgery	13 (93%)	13 (71.2%)	0.35

after.

Table 1 patient characteristic between the group A and group B

## Table 2 Group A: Patient data use lag screw technique

Patient number	Year	Gender	Age	Results	Complications	Screw type	Subluxation	Imaging following	Clinical follow up	Timing of surgery	Surgeo n
1	2002	female	87	good		lag screw		3 months	3 months	immediate*	MT
2	2002	female	89	good/fibrous union		lag screw		6 months	6 months	immediate	AT
3	2002	male	86	good/fusion		lag screw		12 months	12 months	immediate	SY
4	2002	female	82	non union		lag screw		3 months	3 months	immediate	SY
5	2002	female	86	good/fibrous union		lag screw		3 months	12 months	immediate	SY
6	2006	female	85	good/fusion		lag screw		1.5 months	3 months	immediate	JS
7	2006	male	73	good/fibrous union		lag screw		12 months	12 months	immediate*	SY
8	2006	female	69	poor fixation/non union		2 lag screw	yes, retro	4 years		6 week	SY
9	2006	female	89	good/fibrous union		lag screw	yes, retro	12 months	12 months	1 week	SY
10	2008	male	82	good		lag screw	yes, antero	3 months	3 months	immediate*	SY
11	2008	male	47	delayed failure requiring posterior fusion	delayed failure	lag screw		3 month*	3 month*	8 month	SY
12	2008	female	78	good/fusion		2 lag screw	yes, slight retro	3 months	6 months	immediate	AT
13	2009	female	61	good/fusion		lag screw	yes, retro	4 months	8 months	immediate	AT
14	2009	female	87	good		lag screw	no	1.5 months	3 months	immediate	SY

Table 3 Group B: Patient data of Acutrak screw cases

Patient number	Year	Gender	Age	Results	Complications	Screw type	Subluxation	Imaging follow	Clinical follow up	Timing of surgery	Surgeon
15	2008	male	77	non union	trached	Acutrak		4 months		Immediate	SY
16	2009	female	90	good		Acutrak	yes, retro	2 months		Immediate	SY
17	2009	male	74	good/fibrous union		Acutrak	no	8 months	6 months	4 weeks	SY
18	2009	female	63	loss of reduction, required posterior fusion		Acutrak	yes, retro	2 weeks	3 weeks	Immediate	AT
19*	2009	female	89	good/fibrous non union		Acutrak	yes, retro	3 months	2 years	Immediate	SY
20	2010	male	88	loss of reduction/requiring fusion		Acutrak	yes, retro	2 months	2 months	Immediate	SW
21	2010	male	75	good/fibrous union	screw pull out/incidental 6 years later	Acutrak		3 months	3 months	11 weeks	JB
22	2011	female	71	good/fusion	peg	Acutrak		4.5 year	3 months	Immediate	SY
23	2011	male	27	good/fusion		Acutrak		3 months	3 months	Immediate	SY
24*	2011	female	20	failure to reduce/Type III fx		Acutrak		3 months	3 months	Immediate	SY
25	2012	female	81	good		Acutrak		3 months	3 months	Immediate	SY
26	2012	male	17	technical failure to purchase bone		Acutrak	yes, antero	3 months	3 months	immediate	SY
27	2012	male	67	good		Acutrak	yes, retro	3 months	3 months	immediate	SY
28	2013	female	88	good		Acutrak	yes, retro	3 months	3 months	immediate	AT
29	2014	female	80	good		Acutrak		3 months	3 months	immediate	SY
30*	2014	male	73	delayed loss of reduction requiring posterior fusion		Acutrak		1.5 months	1.5 months	6 weeks	SY

# Clinical/radiographic followup results

#### Table 4 Surgical outcome

The results of surgery show a good outcome, defined as either fusion or stable fibrous union, in 11 patients (78%) and 10 patients (63%) of the lag screw and Acutrak screw, respectively. This

	Group A:	Group B:	Excluding
	Lag	Acutrak	Pt 24 and
Result	screw	screw	26
good/fusion/stable			
fibrous union	11 <b>(78</b> %)	10 (63%)	12 <b>(75</b> %)
poor/non union	3 (22%)	6 (37%)	4 (25%)
p value		0.337	0.817

difference is not statistically significant (p=0.337) . Patient #24 had failure of the operation to reduce the fracture and required a Halo followed by a

posterior reduction and fusion. However, this was a type III odontoid fracture with significant ligamentous injury and rotatory and shear component. We believe this fracture would not be adequately reduced from an anterior approach. Patient #26 had an anteriorly displaced coronally oblique fracture that during surgery the screw could not get purchase to the distal fragment and maintain reduction. This case was aborted and the patient was placed in a halo. We believe this was due to the incompatibility of the fragment geometry with anterior reduction approach as well. Excluding patients #24 and #26 yielded a success rate of Acutrak group of 75% ( P=0.817). Other failures from both approaches include



Figure 4 patient #24, type III fracture, unreducible with odontoid screw



loss of reduction and delayed need for posterior fusion. Patient# 21 had a good result at 3 months using the Acutrak

Figure 5 Patient #24after reduction and fixation posteriorly

technique, and 6 years later the screw was observed to have partially backed out as an incidental, asymptomatic finding.

The patient was offered surgery to remove the screw.

# Variables and rates of fusion

Since there was no statistical difference in outcome between the two techniques after adjusting for case selection, we looked at several variables that may have an impact with success of surgery. Specifically, timing of surgery, gender, age greater or less than 70, and surgeon who performed the operation were considered in a univariate fashion.

There was a statistically significant difference in outcome if surgery was delayed greater than 6 week from injury, with only 1 union out 4 cases, P=0.019.. Excluding patient #24 and #26, who are retrospectively deemed technically infeasible for the anterior approach, who both happened to be young, 19 and 17, respectively, age was not a statistically significant variable for fusion rates in this cohort of patient (p=0.11). Also, the choice of surgeon (p=0.561) nor the patient gender (p=0.253) were statistically associated with either outcome.

		Non-	
	Union	union	р
delayed surgery	1	3	
Immediate			
surgery	21	5	0.019
age>70	18	4	
age>70 age<70*	3	3	0.111
Surgeon SY	14	7	0.561

Table 5 Variable and fusion rates

Surgeon AT	4	1	
female	14	4	
male	7	5	0.253

# Discussion

The objective of this paper was to review the clinical and radiographic outcome of the use of the Acutrak 4/5 headless compression screw for unstable type II odontoid fractures at a busy Level 1 Trauma Center. Although fixation of type II odontoid fracture using an anterior odontoid screw is an attractive option with benefits such as direct osteosynthesis and preservation of C1/2 motion, there remain technical and intrinsic fracture patterns that are challenges to successful surgical results. The ideal screw requires "bicortical" purchase from the anterior-inferior C2 to apical cortex. It requires the threaded part of screw to be placed distal to the fracture line if using partially threaded lag screw, and there should be reduction/compression across strong cortical bone. If using a fully threaded screw using a lag technique, the proximal bone need to be over-drilled, ie. a glide hole. The technical challenges include: sizing the correct thread length of lag screw, fully thread screws technique require overdrilling of the proximal C2, small risk of K-wire bending or penetration beyond distal cortex to brain stem in cannulated systems, difficult body habitus such as barrel chest/kyphotic c-spine, and fracture geometry. Poor nutritional status, osteoporosis, age, and delayed timing of surgery has also been cited in the literature for decreased union/healing<sup>9</sup>. Although our study was probably underpowered to show the effect of patients' age on fusion, it confirmed delayed surgical intervention > 6week from injury was associated with lower rate of fusion (p=0.019).

Theoretical pitfall of anterior odontoid screw includes adjacent segment disruption due to the need for C3 body drilling and C2/3 disk disruption.. Due to its variable pitch of the thread that is proximately shallower and distally more aggressive, as the screw is tightened it functionally acts like a lag screw and results in reduction and compression of the fracture fragment without having to calculate precise measurements dependent on a predicted amount of reduction This screw been widely used in many orthopedic applications including scaphoid fracture. Its headless design allows the screw to be countersunk flush with or even beneath the cortex thus minimalizing its profile and decreasing soft tissue irritation. When used as an odontoid screw in our modified technique, there are some notable advantages over the traditional method:

- no need to size the threads as needed for a lag screw
- no need to overdrill C2 body proximal to fracture as needed in the lag technique
- there is bony purchase through the entire length of the screw which is presumed to enhance stiffness

- we have found the Acutrak screw to provide more effective reduction of the fracture fragment intraoperatively
- the use of the O-arm enhances visualization of the adequacy of pre fixation reduction and post fixation screw accuracy
- The headless design allows starting point to be more anterior and steeper thus minimizing the need for C2/3 disk disruption and improving the approach angle which may allow instrumentation in barrel chested and kyphotic patients

In this study, we do not have the data to prove its superiority over the traditional method. However, the senior author has used the Acutrak technique exclusively since 2009 due to relative technical ease and advantages without sacrificing good results. As a result, on average the lag screw was used in 3.2 cases per year while the Acutrak screw was used in 3.8 cases a year. We do not have the prevalence data of all type II odontoid fracture patients to assess if the increased use is truly due to better applicability versus increase incidence of the injury being treated in our institution. As seen in table 1, the two groups being compared have similar patient demographics. The actual surgical good result/fusion rate of Acutrak technique was 75% when the 2 patients that we have learned we would not consider odontoid screw candidates because of their injury types were excluded from analysis. Compared to the lag screw technique result of 78%, with a p value of 0.817, this study suggest that there is no statically significant difference in outcome between the two groups . It is also consistent with published rates in the literature and very good for the eldery.<sup>4,5,7</sup>

Biomechanically, the Acutrak screw has been shown to be superior. Wheeler et al. published a study that evaluated and compared the mechanical strength of the Acutrak screw with an AO 4-mm cancellous screw using anatomic cancellous specimen bone and cancellous bonelike foam. This study found that the Acutrak was able to maintain compression after cyclic loading significantly better than the AO 4-mm cancellous screw .The torque that was required to break fragment contact was also significantly greater for the Acutrak screw compared to 2 other screw types.<sup>10</sup> In 2007, Magee et al. published a paper that compared stiffness and load to failure in human cadavers with Type II odontoid fractures that were stabilized with either a lag or an Acutrak screw. This study found that the stiffness and load to failure were greater for the Acutrak models compared to the lag screw<sup>11</sup> The only clinical report of the use the Acutrak in odontoid fracture comes from Tonosu et al<sup>8</sup>. They reported 1 case in using the Acutrak 4/5 headless compression screw for anterior odontoid fixation in a patient with osteopenia with an acute Type II odontoid fracture. Her 3 month follow-up CT cervical spine showed bone union of C2 with no deformity. A CT cervical spine taken 3 years post fixation continued to show bony union with no degenerative changes. Our results show similar results in using the Acutrak 4/5 headless compression screw for anterior odontoid fixation.

Limitations of our study include retrospective analysis, relative small sample size and short follow-up period, lack of complete and consistent follow up data, especially on complications. Radiologic assessment by the treating physician and lead author is prone to observer bias. The long term complication of a screw backing out after 6 years is a potential issue, and long term follow up imaging may be necessary.

# Conclusion

A good technical understanding of anterior odontoid fixation for Type II odontoid fractures is imperative as the frequency of these fractures become more common in our aging population. Our study suggest that the Acutrak 4/5 headless compression can provide equivalent outcome in selected anterior odontoid fixation for acute Type II fractures as compared to our cohort of patient using the traditional lag technique. Larger prospective, randomized trials with long-term follow-up would better determine the efficacy in using the Acutrak 4/5 screw in the anterior odontoid fixation of Type II odontoid fractures.

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