ORIGINAL ARTICLE

Inter-observer reliability of detecting Dynesys pedicle screw using plain X-rays: a study on 50 post-operative patients

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Abstract Dynamic stabilisation system for the spine (Dynesys) relies on titanium screw purchase within the pedicle. Decision on osseointegration is important especially when the patient becomes symptomatic following initial good outcome. Loose screws make the construct non-functional especially in symptomatic patients. Removal of Dynesys may become necessary to control patient's symptoms. In this study, we report interobserver reliability of X-ray for the interpretation of Dynesys pedicle screw osseointegration based on the diagnosis of "halo zone" and "Double halo zones" surrounding loose screw. Lumbar spine X-ray images of 50 patients in two views (AP and lateral) were selected from a random sample of 420 Dynesys patients. The total number of pedicle screws reviewed in this study was 260. The investigators (observers) were asked to state whether or not each pedicle screw is loose using "radiolucent zone sign". Observers were two expert orthopaedic spine consultant surgeons and one expert consultant radiologist and four specialist registrars (SpR) in orthopaedics and radiology. SpR assessments were repeated after 4 months with instructions to use "double-halo sign" for loose screws. The evaluation of interobserver agreement was performed by obtaining a Kappa (K) index. Using "radiolucent zone sign", Kappa Index (KI) among three consultants was 0.2198 at 95% CI (0.0520, 0.4916) while for all of the seven assessors (3 consultants and 4 SpR), KI was 0.1462 at 95% CI (0.0332, 0.2592). The use of "double-halo sign" was associated with KI of 0.666 at 95% CI (SE 0.83) among all of the 4 SpR. Based on plain X-ray "radiolucent zone sign", the inter-observer reliability of detecting loose Dynesys

pedicle screw was poor (Kappa index of 0.2). On the other hand, using plain X-ray "double-halo sign" was associated with improved inter-observer reliability and validity.

Keywords Pedicle fixation · Lumbar spine · Dynesys

Introduction

Dynesys[®] (Fig. 1) is designed to off-load the diseased spinal segment [36] while maintaining a controlled movement at the treated disc level(s) [26]. It is a pedicle screw construct. On each side of the spine, screws are joined through flexible cord (made of *Sulene* polyethylene terephthalate) and flexible spacers (made of polycarbonate urethane). There is no cross link between the two sides.

Dynesys pedicle screws (Fig. 2) are made of titanium alloy (*Protasul* [®]100) and since 2002, Hydroxyapatite (HA) coated screws were made available. The screws are self-tapping and are conical in shape. Different sizes are available; the smallest is 5.2 cm (length) \times 35 mm (cross section) and the largest is 8.0 cm \times 55 mm. Placement of screw can be subfacetal (in posterior approach surgery) or screws can be positioned lateral to the facet joints (in posterolateral approach) [5]. The manufacturer recommended posterolateral approach with screws placed lateral to facet joints.

Dynesys was successful in controlling symptoms associated with degenerative disc disease as shown by a previous papers by the same authors [6, 7]. Early clinical outcome was also promising in the Food and Drug Administration (FDA) trial [47]. Bordes-Monmeneu et al. [2] reported a reduction of 35 points in Oswestry Disability Index (ODI) following the application of Dynesys in 94 patients for a period of 14–24 months.

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Fig. 1 Dyensys $\ensuremath{^{\textcircled{\$}}}$ implant consists of: titanium pedicle screws, cords and spacers



Fig. 2 Dynesys HA coated pedicle screw

Being a pedicle screw system, the construct loading may force the screws to move within the pedicle and loose their bone-purchase. Reports on the incidence of loose pedicle screw based on "halo zone sign" vary in the literature and depends on the interpreter's experience (3.6–17%) [12, 15, 37, 41]. Similarly, loosening within pedicle screw lumbosacral fusion is reported [28]. Some studies were associated with interestingly high rates than others. Ohlin et al. (1994) [27] reported an incidence of 20.8% in his series of 153 patients.

Identifying symptomatic loose screws is important. A loose pedicle-dependant construct may move with spinal movements and trigger painful paraspinal muscle spasms. The decision to subject the patient for a second surgery with or without reinstrumentation must be evaluated carefully. Conventional plain X-rays are relatively easy to obtain. Standard AP and Lateral views are helpful. However, these views are limited with the information they provide.

Early diagnosis of screw loosening can save the patient not only painful spasms but also late macromovements and possible serious neural damage or screw breakage [23, 29, 30].

On the other hand, asymptomatic metal failure (loosening or breakage) may not need more than monitoring. Schnake et al. [37] reviewed 26 patients and showed that implant failure in four patients was not related to patient satisfaction or back pain.

In this study, we are have challenged our assessors to make a diagnosis on loose pedicle screws based on the identification of two signs; namely "halo zone sign" and "double-halo sign".

Material and methods

Lumbar spine X-ray images of 50 patients in two views (AP and lateral) were selected from our prospective cohort of 420 patients. Patients' data was presented on excel spreadsheet format from when we first used Dynesys (September 2000) until now. For the purpose of this study, we decided to choose an end point as (June 2008). Clinical data collection is ongoing for the rest of the cohort.

Simple randomisation was achieved through computerised random number generator (RNG) method. Patients were operated on and followed up at the Conquest Hospital in Hastings, UK.

The study was approved by the Committee on Ethics in Research of the hospital.

Anterioposterior and lateral radiographs were obtained from the digital PACS[®] radiographic imaging review system. Each view was magnified and the contrast was adjusted to obtain the best accurate image. Images then saved as JPEG files with an average size of 85 K byte. Each photograph showed no more than three vertebral levels and their corresponding pedicle screws. Additional images were made to show vertebra/screws if they exceeded three levels. Authors were made aware of any additional pictures. Pictures were then coded alphabetically and the file name was amended to include AP or Lateral views with further images if present. Photos were deployed onto a CD-ROM and distributed among observers. All of the seven reviewers were supplied with scoring sheets to record their results.

For the first part of this study, the investigators were asked to state whether or not each pedicle screw is loose (total of 260 pedicle screws) based on the presence of "a radiolucent halo zone sign" surrounding suspicious screws. In AP views, a lucent ring surrounding the screw is considered "halo zone" and it is confirmed in lateral view as tracking line along part or the entire length of the screw. Assessors were made aware of the possible silhouette shadow of bowel gases. All of the 260 screws were evaluated independently by all of the seven observers.

Observers were composed of seven physicians; two expert orthopaedic spine consultant surgeons, one expert consultant radiologist with special interest in musculoskeletal radiology and four specialist registrars (SpR trainees) in orthopaedic surgery and radiology. SpRs were in their 3rd–4th year of specialist training programme and they spent at least three months with the two "expert" consultants doing Dynesys. Consultants were considered "experts", while Specialist Registrars were considered "trainees".

Four months later, all of the four SpR(s) were asked to repeat their assessment using "double-halo sign" for the diagnosis of loose screws. "Double-halo" was described as a radiolucent rim surrounding the screw which is framed by rim of radio-opique dense bone trabiculae.

Statistical methods

The evaluation of interobserver agreement was performed by obtaining a Kappa index (KI). For continuous variables comparison, the Fisher's exact test was employed, with a significance level of 0.05.

Z value at CI 95% was used to compare the significance in specificity of both signs.

Results

"Halo zone sign"

Table 1 shows the proportions of loose screws identified by each of the seven evaluators based on their interpretation of the X-ray films. The mean number of screws identified as being loose by experts was 11 (i.e. 4.2% of screws), while the mean number of loose screws identified by trainees was 59.3 (i.e. 23%).

Table 2 shows that the Kappa Index among three experts was 0.2198 at 95% CI (0.0520–0.4916) while for all of the seven assessors (3 Experts and 4 trainees), Kappa index was 0.1462 at 95% CI (0.0332–0.2592).

"Double-halo sign"

Table 3 reports the incidence of screw loosening based on "double- halo sign". The mean number for all of the four assessors for was 8.5%.

| Table 1 | Percentage | of loose | screws | based | on | "halo | zone | sign" | |
|---------|------------|----------|--------|-------|----|-------|------|-------|--|
|---------|------------|----------|--------|-------|----|-------|------|-------|--|

| Assessors | Number ^a (percentage | |
|-----------------------------------|---------------------------------|--|
| Observer 1 (consultant) | 9 (3.4%) | |
| Observer 2 (consultant) | 11 (4.2%) | |
| Observer 3 (consultant) | 13 (5%) | |
| Observer 4 (specialist registrar) | 9 (3.4%) | |
| Observer 5 (specialist registrar) | 56 (21.7%) | |
| Observer 6 (specialist registrar) | 59 (22.8%) | |
| Observer 7 (specialist registrar) | 113 (43.7%) | |

^aNumbers and percentages out of 260 X-ray pictures of screws

 Table 2 Percentage of Kappa index for pedicle screw loosening based on "halo zone sign"

| Kappa/CI | 3 Experts | 3 Experts and 4 SpR |
|---|--------------------------------|-------------------------------|
| Kappa index 95% confidence interval | 0.2198 CI (-0.0520, 0.4916) | 0.1462 CI (0.0332, 0.2592) |

Table 3 Percentage of loose screws based on "double-halo sign"

| Assessors | Number ^a (percentage) |
|-----------------------------------|----------------------------------|
| Observer 4 (specialist registrar) | 19 (7.3%) |
| Observer 5 (specialist registrar) | 22 (8.4%) |
| Observer 6 (specialist registrar) | 24 (9.2%) |
| Observer 7 (specialist registrar) | 24 (9.2%) |

^aNumbers and percentages out of 260 X-ray pictures of screws

 Table 4
 Percentage of Kappa index for pedicle screw loosening based on "double-halo sign"

| Kappa/CI | 4 SpR |
|---------------------------------------|-------|
| Kappa index (95% confidence interval) | 0.666 |
| Standard error | 0.83 |

Table 4 shows the Kappa Index among the same four trainees after changing the instructions. KI was 0.666 at 95% CI (0.496–0.836), SE 0.83.

Table 5 indicates that "Double halo sing" has more specificity for the diagnosis of loose screws than "halo zone sign".

Table 6; based on the assessment of the senior orthopaedic consultant surgeon, overall incidence was 3.4%. Table shows the breakdown of loose versus non-loose for both HA and non-HA screws. Average time to X-ray follow up following surgery was 40.9 months (range from 20 to 74 months). In October 2002, we have moved away from non-HA coated screws because of the potential risk of loosening.

 Table 5
 Both signs are sensitive for the diagnosis, however; "Double halo sign" has more specificity for the diagnosis of loose screws than

 "halo zone sign"

| | Sensitivity | Specificity | Positive predictive value | Negative predictive value |
|------------------|-------------|-------------|---------------------------|---------------------------|
| Halo zone sign | 1 | 0.8047 | 0.155 | 1 |
| Double Halo sign | 1 | 0.940 | 0.375 | 1 |

Specificity difference was significant with Z value of 4.604 at CI 95%. Predictive values are low because of the low incidence of screw loosening among the patients cohort

 Table 6
 Based on the assessment of the senior orthopaedic consultant surgeon, overall incidence was 3.4%

| | HA coated | Non-HA coated | Total |
|-------------|-----------|---------------|-------|
| Loose screw | 3 | 6 | 9 |
| Not loose | 41 | 0 | 41 |
| Total | 44 | 6 | 50 |

Table shows the breakdown of loose versus non-loose for both HA and Non-HA screws

Discussion

"Halo zone sign" analysis: Interobserver Error

The first part of this study showed poor agreement between all observers (Kappa Index 0.1462) see Table 7 also for reference [20]. Even at expert's level, agreement was not satisfactory to be regarded as reliable (KI 0.2198). Authors were not sure whether the halo surrounding a pedicle screw was anything but the bowel gas shadow interface. Different angles of projection of screws added to the difficulty in making the diagnosis on AP views especially when Wiltse approach was used during surgery. Lateral radiographs were used for confirmation whereas the AP views were useful for initial diagnosis.

"Double-halo sign" analysis:

In the second phase and when the study was repeated at trainee level, KI was improved significantly. Agreement on loose screws was considered substantial (KI 0.666) Table 6 [20]. Authors were more confident to comment on loose pedicle screw when the immediate radiolucent zone was

Table 7 Interpretation of Landis and Koch (1977) [20]

| • | |
|-------------|------------------|
| Kappa index | Agreement |
| 0.00 | Less than chance |
| 0.00-0.20 | Slight |
| 0.21-0.40 | Fair |
| 0.41-0.60 | Moderate |
| 0.61-0.80 | Substantial |
| 0.81-1.00 | Almost perfect |

surrounded by a rim of radiopque dense bone trabiculae. This sign was more reliable and its specificity was significantly superior than halo-zone sign (Z value 4.604 at CI 95%) Table 7.

Effect of examiners' experience and specialty

Trainee reported loose screws in as much as five times as the expert observers when using "halo zone sign" 23, 4.2% respectively. This was statistically significant (P < 0.05).

The senior radiologist reported a higher figure than both orthopaedic senior authors; 5, 4.2 and 3. 4%, respectively. However; this was not statistically significant (P > 0.05).

Pedicle screw fixation

Approximately 60% of screw fixation strength in the lumbar region is in the pedicle while the cancellous bone within the vertebral body adds no more than 15-20% of strength. On some occasions, the benefits outweigh the risks and advancing the screw to the anterior vertebral cortex offers 20-25\% strength [46, 50]. Whereas in the sacral area, the anterior cortex contributes to 60% of the overall screw strength.

Factors influence screw purchase

There are multiple factors which may affect screw purchase directly or indirectly. Some of them are related to screws' thread design, shape, length, cross-section size or surface roughness. Other factors are related to boneimplant interface e.g., using enhancers like HA or bone cement. Some other factors are generic and may be related to patients themselves, e.g. osteoporosis (see Table 8).

Screw failure

One of the major disadvantages of pedicle screw system is late onset backpain. Lonstein et al. [22] examined a total of 879 patients (total screws were 4,790) with rigid pedicle screw fusion. Of which 1,102 screws (23%) were removed due to "pseudarthrosis" or "pain related to instrumentation". Being a pedicle construct, Dynesys patient might encounter postoperative pain [8]. Persistent pain should be

Table 8 Factors influence screw purchase in DDD

| Screw thread design [9, 18, 19, 38] |
|--|
| Screw shape [23] |
| Screw surface roughness [9, 14, 18, 21, 38] |
| Screw length [9, 18, 38] |
| Screw cross-section size [9, 18, 38] |
| Osteoporosis [40] |
| Use of bone-implant interface enhancers, e.g., HA [4] or bone cement |

investigated to exclude malposition of screws (1-12.9%) of patients) [2, 12, 15, 41], recurrence of disease (21%) of patients) [37], infection (1.2–3.2%) [2, 15, 41] metal breakage or loosening (12–19%) of patients) [15, 37, 41]. Symptoms may arise from the adjacent spinal segments and it must be investigated as it may require surgical treatment (2.5–29%) of patients) [12, 37, 41].

In some patients no cause can be identified for patients' backpain (8%) [37]. Some surgeons might blame it to "instrumentation" [22] while others believe it is attributed to poor osseointegration of metal screw within the pedicle [38] and leaves the spinal construct dysfunctional.

Poor screw anchor can results in micromotion at the distal end and in distraction construct, like Dynesys, this may lead to stress shielding. Lu et al. [24] found that cyclic loading with 30% of the yield load of human vertebrae significantly increased microcrack density in the vertebral trabeculae at 20,000 cycles of loading but the vertebrae did not fail. This level of cyclic load may be insufficient to cause failure of the entire pedicle screw system in a vertebra but sufficient to cause damage in bone adjacent to the screw. In addition, Movement between screw threads and bone inhibits bone formation, revascularization and remodeling of dead bone. Movement causes the screw to become enveloped by fibrous tissue in response to necrosis and resorption of adjacent dead cortical bone [35]. This results in a radiologically discernible radiolucent "halo" about the screw, a certain sign of screw loosening [33, 35]. Eventually the distraction principle of the construct is lost.

It is rather difficult to predict which screws are going to be loose or which patients are more likely to become symptomatic. Similarly, there is no specific time scale to indicate the most crucial period.

Decision to take the screws out

Identifying symptomatic loose screws is important. A loose pedicle-dependant construct may move with spinal movements and trigger painful paraspinal muscle spasms. The decision to subject the patient for a second surgery with or without reinstrumentation must be evaluated carefully. Conventional plain X-rays are relatively easy to obtain. Standard AP and Lateral views are helpful. However, these views are limited with the information they provide. Our observers could not see a cross sectional view of all screws from a single AP projection due to different projections of the screws in axial and coronal planes. Making a comment on the "halo zone" surrounding all screws from a single AP view is not accurate. Similarly, on the lateral view, the two screws at the same vertebra may be superimposed on each other. The diagnosis of "halo zone" from the lateral radiograph is more difficult and less precise.

Quantifying the lucency is another challenge. Sandén et al. [33] used 1 mm width to differentiate thin and wide radiolucent zones disregarding the length of the lucency. Tokuhashi et al. [44] used 1 mm or greater circumferential lucency around a screw from two or more digitalized plain radiographic directions.

The scientific bases for choosing 1 mm as a cut-off point are not clear. In addition, magnification effects of digital radiographs must be taken into account. Calibration with the screw dimensions might be useful. Furthermore,

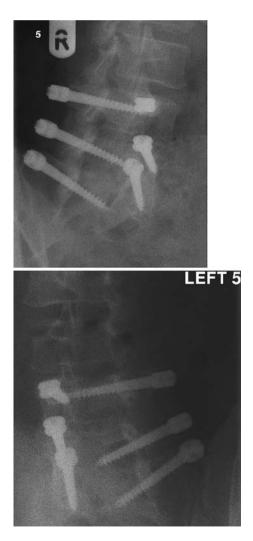


Fig. 3 Right and left 45° oblique views

radiolucency along the entire length of the screw is understandingly more important than isolated lucency around the tip of the screw where cancellous vertebral bone account for not more than 20% of screw strength in the lumbar vertebra [46, 50].

Authors of this study believe that 45° "oblique views" (Fig. 3) was not superior to standard AP view. In fact, a single oblique view necessitates almost double the radiation dose. To sum up, the radiation exposure for two oblique views was three times the standard radiation dose of a single "AP view" and it was unjustified for the low quality of information they provide.

Current practice for the diagnosis at our Spinal Unit

The senior author of this paper prefers screening suspicious screws under direct fluoroscopic control at the surgical room. The C-arm can be adjusted to follow vertebral inclinations and face the screw's head directly. The "double halo sign" can be identified much easier.

The difficulty with applying this diagnostic procedure is to all suspicious screws arises from the fact that it requires the availability of resources and expertise. It is best to combine visualisation of screws with another diagnostic or therapeutic procedures, e.g., spinal probe or caudal epidural injections (Figs. 4, 5, 6]

Measures to reduce screw loosening

Improving screw-bone bonding was the target for many studies [13, 16, 31, 32, 34, 39, 42, 45, 48, 49]. The most successful among these was the use of plasma-sprayed HA screws [13, 16, 32, 34, 45, 49]. Osteoblast adhesion and differentiation is enhanced when bioactive titanium 1491



Fig. 5 Different screw projections with overlapping bowel gas shadow make "radiolucent zone" difficult to interpret

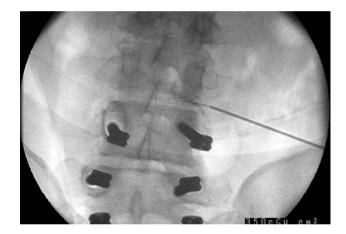


Fig. 6 loose right L4 and right L5 screws confirmed by fluoroscopy. A spinal probe was applied in the same time for L3-L4 disc level

Fig. 4 "Double halo sign" surrounding right L4 screw; inner radiolucent zone surrounded by an outer radioopaque rim of dense bone trabeculae



implant is used in comparison to titanium alone [49]. The bone-implant interface was different from mineralizing bone matrix or osteoid. Histologicaly, the interface was rich in proteoglycans and glycoproteins [3, 10, 11]. In addition, osteoblastic matrix proteins such as osteopontin and alpha HS—glycoprotein has been demonstrated to facilitate interface synthesis [17, 25].

Hydroxyapatite coating can increase surface area which improves the biomechanics as well as the load bearing capacity of the structure. HA has been shown to decrease corrosion rates and accelerate the rate of bone formation and maturation [1, 43]. HA-bone interface exhibit more organised bone pattern and a superior degree of mineralisation than for other materials. The bone-HA interface has been proven to be stronger than the HA-implant interface [1, 43].

Limitations of this study

- The difference in KI reliability for the second study might be related to more careful interpretation of loose screw. It is difficult to disprove it in the absence of intraobserver record of the first study.
- The second review involved only trainees. It would be of greater significance to involve all of the seven assessors.

Conclusion

The Inter-observer reliability of detecting loose Dynesys pedicle screw using "double-halo sign" was associated with improved inter-observer reliability and validity. We suggest using "double halo sign" to describe established loose pedicle screw.

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Conflict of interest statement None.

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