Computed tomographic analysis of the quality of trunk muscles in asymptomatic and symptomatic lumbar discectomy patients

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Abstract

Background: No consensus exists on how rehabilitation programs for lumbar discectomy patients with persistent complaints after surgery should be composed. A better understanding of normal and abnormal postoperative trunk muscle condition might help direct the treatment goals.

Methods: A three-dimensional CT scan of the lumbar spine was obtained in 18 symptomatic and 18 asymptomatic patients who had undergone a lumbar discectomy 42 months to 83 months (median 63 months) previously. The psoas muscle (PS), the paraspinal muscle mass (PA) and the multifidus muscle (MF) were outlined at the L3, L4 and L5 level. Of these muscles, fat free Cross Sectional Area (CSA) and fat CSA were determined. CSA of the lumbar erector spinae (LES = longissimus thoracis + iliocostalis lumborum) was calculated by subtracting MF CSA from PA CSA. Mean muscle CSA of the left and right sides was calculated at each level. To normalize the data for interpersonal comparison, the mean CSA was divided by the CSA of the L3 vertebral body (mCSA = normalized fat-free muscle CSA; fCSA = normalized fat CSA). Differences in CSA between the pain group and the pain free group were examined using a General Linear Model (GLM). Three levels were examined to investigate the possible role of the level of operation.

Results: In lumbar discectomy patients with pain, the mCSA of the MF was significantly smaller than in pain-free subjects (p = 0.009) independently of the level. The mCSA of the LES was significantly smaller in pain patients, but only on the L3 slice (p = 0.018). No significant difference in mCSA of the PS was found between pain patients and pain-free patients (p = 0.462). The fCSA of the MF (p = 0.186) and of the LES (p = 0.256) were not significantly different between both populations. However, the fCSA of the PS was significantly larger in pain patients than in pain-free patients. (p = 0.012).

The level of operation was never a significant factor.

Conclusions: CT comparison of MF, LES and PS muscle condition between lumbar discectomy patients without pain and patients with protracted postoperative pain showed a smaller fat-free muscle CSA of the MF at all levels examined, a smaller fat-free muscle CSA of the LES at the L3 level, and more fat in the PS in patients with pain. The level of operation was not found to be of importance. The present results suggest a general lumbar muscle dysfunction in the pain group, in particular of the deep stabilizing muscle system.
Background

Following lumbar discectomy, residual complaints persist to some degree in 28% [1] to 74.6% [2] of patients and are a common diagnostic and therapeutic problem. Previous studies have focused on the radiological identification of possible pain-inducing structures in failed back surgery patients [3-5]. However, recurrent pain following lumbar surgery is clinically often nonspecific, and imaging techniques frequently fail to demonstrate a structural reason for the pain. As a consequence, no consensus exists on the management of such residual pain, especially if technical investigations are negative. Exercise therapy following surgery has been shown to have a beneficial effect [6-8], but how rehabilitation programs should be composed remains a controversial issue [7].

As in nonspecific chronic low back pain (LBP) [9-11], the paraspinal muscles seem atrophied in patients with postoperative LBP [12-14]. Postoperative trunk extensor atrophy has been shown to be accompanied by a decrease in muscle function, particularly in trunk extension force [13]. The most medial of the three paraspinal muscles (PA), the multifidus (MF), has a major trunk-stabilizing function [5,15]. In nonsurgical LBP patients, MF atrophy has been demonstrated, and current physiotherapy practice is often focused on localized spine-stabilizing muscle exercises [16,17].

Previous studies have reported on the Computed Tomography (CT) quality of the back muscles of lumbar discectomy patients [12-14]. Muscle atrophy has been scored on CT-images of patients with good and poor recovery 2 to 5 years after surgery for spinal stenosis or disc herniation [14]. In the study by Sihvonen et al, distinct back muscle atrophy was much more prevalent in patients with poor results. Muscle disuse was held responsible for this finding, because muscle atrophy was not restricted to the level of operation in the failed back group [14]. The rating of muscle atrophy was, however, partially based on a visual impression of back muscle density, without specification of muscle mass. Cooper et al. demonstrated simultaneous wasting of the PA and the psoas (PS) in chronic LBP (mainly surgical patients) compared to acute LBP patients [12]. The MF was not studied separately [12]. Mayer et al. described PS and erector spinae atrophy in spinal surgery patients (27 mechanical/chemical discectomy patients and 7 lumbar fusion patients) compared to controls without back pain. Muscle atrophy was documented through a significant decrease in muscle density on CT scan 3 months after surgery [2]. Whether or not patients experienced postoperative pain was however not taken into account. The MF - which is retracted in standard lumbar discectomy and in lumbar fusion - was not investigated separately. Motosuneya et al. studied back muscle atrophy on MRI images after five surgical procedures [18]. They found significant back muscle atrophy after anterior lumbar interbody fusion, posterior lumbar interbody fusion and posterolateral fusion, but not after laminectomy and nucleotomy. The MF was not investigated separately, and most patients had no or occasional mild LBP.

To our knowledge, differences in muscle quality of the isolated MF between lumbar discectomy patients with and without pain have not been studied yet.

Therefore, the present study was designed to investigate possible differences in muscle condition of 3 trunk muscles, particularly the MF, in lumbar discectomy patients with pain and without pain. The muscles were examined at three levels to study the possible influence of the level of operation.

Methods

Study design

After obtaining approval from the Ghent University Ethics Committee, lumbar discectomy patients with and without pain were included in the study. A volume CT scan of the lumbar region (L3 lower endplate to S1 lower endplate) was performed to screen for old and new lumbar disorders. In case of normal postoperative findings, reconstructions were made through the lower endplates of L3, L4 and L5 for measurement of the total and fat-free muscle cross-sectional area (CSA) of the isolated MF, lumbar erector spinae (LES) and PS on both the left and right side. Fat area was calculated as the subtraction of fat-free muscle CSA from total CSA.

Subjects

Thirty-six patients with a history of L5-S1 lumbar discectomy, participated in the study. They were divided into a pain-free postdiscectomy group (n = 18) and a postdiscectomy group with pain (n = 18), based on their pain history and the results of a Visual Analogue Scale (VAS) for pain. Pain-free patients had experienced no or occasional back pain following the operation. The cut-off point was set at 1.5 on VAS since 7 patients scored between 0.5 and 1.5 on VAS, stating that this score reflected no real pain, but rather awareness of their back [19].

Disc resection was unilateral in 20 (56%) and bilateral in 16 (44%) cases. Time since surgery ranged from 12 months to 89 months (mean 59 months). All participants read and signed an informed consent form. Their clinical data are presented in table 1.

Exclusion criteria

Overall exclusion criteria were lumbar scoliosis, hip disorders, pregnancy within the last year, a history of central neurological impairments, and major pathological conditions such as a malignant tumour or uncontrolled...
systemic disease. Patients with abnormal postoperative CT-findings were also excluded from the study. These abnormal findings included recurrent disc herniation or new disc herniation with compression of the spinal cord or nerve root compression, spinal stenosis, spondylolisthesis, spinal tumour or pseudomeningomyelocele, degenerative narrowing of the lateral recess with compression of neural structures, and stress fracture of the vertebral arch.

**Procedure**

**Interview, clinical examination, questionnaires**

Clinical evaluation of outcome included an interview and a neurological examination by an independent observer, and standard questionnaires (Quebec Back Pain Disability Questionnaire (QBPDS)[20-22], VAS for pain, Multidimensional Pain Inventory Part I (MPI) [23,24] and TAMPA scale for kinesiophobia) [25].

**Computed tomography**

A 4-slice CT-scan (Somatom Volume Zoom, Siemens Medical Systems, Germany) was used at 140 kV and 200 mAs with a slice collimation of 1.25 mm and a pitch of 0.75. The patient was scanned in prone position from the lower endplate of the L3 to the S1 vertebral body, without contrast administration. Adjacent 5-mm reconstructions were made in a soft-tissue kernel (B30s, medium smooth). All scans were evaluated on a Leonardo (Siemens Medical Solutions, Germany) workstation by a single radiologist, blinded for the patient’s complaints. Five-mm thickness reconstructions were made through the lower endplate of the L3, L4 and L 5 vertebral bodies in a standard fashion (figure 1).

**Table 1 Questionnaire scores and clinical characteristics of the lumbar discectomy patients**

|                        | Discectomy, no pain | Discectomy with pain | P-value |
|------------------------|---------------------|----------------------|---------|
| N                      | 18                  | 18                   |         |
| Gender                 | male                | 8                    | 8       |
|                        | female              | 10                   | 10      |
| Age (yrs) Mean (SD)    | 44.39 (± 9.27)      | 49.72 (± 9.33)       | 0.094   |
| BMI¹ (%) Mean (SD)     | 25.74 (± 3.36)      | 26.02 (± 3.36)       | 0.807   |
| Pain on VAS² (cm) Mean (SD) | 0.69 (± 0.65) | 4.7 (± 1.5)           | <0.001  |
| Radicular pain         |                     |                      |         |
| Low back pain          |                     |                      |         |
| Time since surgery (months) Mean (SD) | 56.00 (± 18.72) | 61.50 (± 14.40)       | 0.405   |
| Duration pain before operation (months) | 57.06 (± 78.25) | 62.12 (± 58.09)       | 0.427   |
| motor                  | No paresis          | 16                   | 13      |
|                        | paresis             | 2                    | 5       |
| sensibility            | Normal              | 12                   | 12      |
|                        | Abnormal            | 6                    | 6       |
| Reflexes               | Normal              | 15                   | 12      |
|                        | Abnormal            | 3                    | 6       |
| Lasègue                | Positive            | 0                    | 3       |
|                        | Negative            | 18                   | 15      |
| Kemp                   | Positive            | 1                    | 5       |
|                        | Negative            | 17                   | 13      |
| Slump                  | Positive            | 3                    | 5       |
|                        | Negative            | 15                   | 13      |
| QBPDS ³ Mean (SD)      | 14.41 (± 10.81)     | 41.72 (± 18.18)      | <0.001  |
|                        | Min-max             | 0-36                 | 16-75   |
| MPI ⁴ Mean (SD)        | 45.71 (± 16.12)     | 75.69 (± 20.68)      | <0.001  |
|                        | Min-max             | 17-83                | 45-108  |
| TAMPA Mean (SD)        | 33.50 (± 9.71)      | 39.56 (± 6.33)       | 0.041   |
|                        | Min-max             | 10-47                | 27-49   |

¹Body Mass Index; ² Visual Analogue Scale; ³ Quebec Back Pain Disability Scale; ⁴ Multidimensional Pain Inventory.
limits (0 -250 HU) was selected. Fat CSA was calculated as the difference between total CSA and fat-free muscle CSA. The CSA of the LES was calculated by subtracting the MF CSA from the PA CSA. The CSA of the L3 vertebral body was measured to normalize the data: each CSA was divided by the CSA of this body, resulting in normalized fat-free muscle CSA data (mCSA) and normalized fat CSA (fCSA) data.

CT Measurement Reliability

All measurements were performed by the same examiner. Intratester reliability was assessed by repeated measurement of 20 of the 36 scans. The assessment of measurement repeatability showed good agreement between the two measurements for PS (ICC = 0.92), LES (ICC = 0.97) and MF (ICC = 0.96), indicating that the measures were reliable.
Data Analysis

Descriptive statistics were used to analyse patient characteristics and clinical findings.

Mann-Whitney-U tests were performed to investigate differences in patient group characteristics. For each muscle investigated (MF, LES, PS) a repeated measures analysis of variance with 3 factors was performed to investigate possible differences in mCSA and fCSA between pain-free and pain patients. The within subject factors were ‘group’ (with 2 sublevels: pain and no pain) and ‘level of operation’ (with 2 sublevels: L4 discectomy and L5 discectomy). The within subject factor was ‘slice’ (L3 slice/L4 slice/L5 slice).

The statistical analyses were performed with SPSS 15.0 software (SPSS, Chicago, IL). Statistical significance was set at \( P < 0.05 \).

Results

The asymptomatic and symptomatic lumbar discectomy group did not significantly differ in age, gender, Body Mass Index (BMI), duration of pain before surgery and time elapsed since surgery (table 1). QBPSD (\( p < 0.001 \)), MPI (\( p < 0.001 \)) and TAMPA (\( p = 0.039 \)) outcome scores were significantly higher in the pain group.

For both groups, the results of the mCSA and fCSA measurements of the LES, MF and PS at the three levels, and of the CSA of the L3 lower endplate are shown in table 2.

Normalized fat-free muscle CSA (mCSA)

Multifidus

No significant interactions were found between the factors. The factor ‘group’ (\( p = 0.009 \)) was significant. The mCSA was smaller in patients with pain compared to pain-free patients. The factor ‘level of operation’ (\( p = 0.796 \)) was not significant. The factor ‘slice’ was significant (\( p < 0.001 \)): the mean mCSA at the L3 slice was significantly smaller than on the L4 slice (\( p < 0.001 \)) and on the L5 slice (\( p < 0.001 \)); the mean mCSA on the L4 slice was significantly smaller than on the L5 slice (\( p < 0.001 \)).

Lumbar erector spinae

Because a significant interaction was found between the factors ‘group’ and ‘slice’ (\( p = 0.049 \)), comparisons between the two study groups were performed for each slice separately. Next, comparisons between slices were done for both patient groups. On the L3 slice, mCSA of the LES was significantly larger in pain-free patients than in pain patients (\( p = 0.016 \)). On the L4 and L5 slice, no significant difference in mCSA of the LES was found between both patient groups.

Although a significant interaction was found for the factors ‘group’ and ‘slice’, the analysis for both groups separately revealed the same results: the factor ‘slice’ was significant (\( p < 0.001 \)); the mean mCSA at the L3 slice was significantly bigger than at the L4 slice (\( p < 0.001 \)) and the L5 slice (\( p < 0.001 \)); mean mCSA on the L4 slice was significantly larger than on the L5 slice (\( p < 0.001 \)).

The factor ‘level of operation’ was not significant (\( P = 0.638 \)).

Normalized fat CSA

Multifidus

No significant interactions were found between the factors. The factor ‘slice’ was significant (\( p < 0.001 \)): the mean fCSA on the L3 slice was significantly smaller than on the L4 (\( p < 0.001 \)) and the L5 slice (\( p = 0.001 \)); the mean fCSA on the L4 slice was significantly smaller than on the L5 (\( p < 0.001 \)). The factors ‘group’ (\( p = 0.186 \)) and ‘level of operation’ (\( p = 0.146 \)) were not significant.

Lumbar erector spinae

No significant interactions were found between the factors. The factors ‘group’ (\( p = 0.258 \)), ‘level of operation’ (\( p = 0.131 \)) and ‘slice’ (\( p = 0.208 \)) were not significant.

Discussion

Pain-free patients compared to pain patients

MF and LES

Present findings

The results suggest atrophy of the MF at the three levels examined in the postoperative pain patients. Besides MF atrophy, LES atrophy was present in the pain patients at the L3 level only. Why LES atrophy was limited to the L3 level is fairly difficult to explain, especially since no surgical intervention was performed at this specific level and since there is no segmental innervation for the LES. It was hypothesized that the L4 and L5 levels also showed LES atrophy, but
that muscle atrophy at these levels is more difficult to
detect, because of the significantly smaller mCSA of the
LES at the lower levels in all patients.

A few imaging studies have described back muscle
atrophy in postoperative discectomy patients. Sihvo-
 nen et al. compared patients with good and poor
results 2 to 5 years after surgery for spinal stenosis or
disc herniation and found distinct back muscle atro-
phy in patients with poor results [14]. Mayer et al.
reported a significantly lower back muscle density in
spinal surgery patients compared to controls without
back pain [13]. Motosuneya et al. studied back muscle
atrophy in 5 lumbar surgery groups by measuring the
CSA of the back muscles before and after surgery
[18]. They documented a decrease in back muscle
CSA in all groups, but the decrease was only signifi-
cant in the lumbar fusion groups [18]. There was no
significant difference in back atrophy regarding pain,
as assessed using the Japanese Orthopaedic Associa-
tion score for the management of LBP [18]. However,
only 4 out of 49 patients reported frequent mild or
occasional LBP [18].

| Section          | Muscle | Discectomy, no pain | Discectomy with pain |
|------------------|--------|---------------------|----------------------|
| Bony CSA         | L3 lower endplate cm² | 15.98 ± 2.70 | 15.30 ± 2.65 |
| Fat-free muscle CSA | L3 lower endplate cm² | 21.37 ± 6.65 | 18.71 ± 5.56 |
|                  | LES    | 34.57 ± 8.36        | 28.62 ± 6.31         |
|                  | MF     | 13.25 ± 3.38        | 10.95 ± 3.44         |
|                  | L4 lower endplate PS | ±             | ±                    |
|                  | LES    | 25.60 ± 7.16        | 21.79 ± 5.06         |
|                  | MF     | 17.22 ± 3.59        | 14.38 ± 3.97         |
|                  | L5 lower endplate PS | ±             | ±                    |
|                  | LES    | 14.17 ± 6.31        | 10.78 ± 5.03         |
|                  | MF     | 19.49 ± 3.79        | 15.56 ± 3.32         |
| Normalized fat-free muscle CSA | L3 lower endplate | 1.33 ± 0.29 | 1.21 ± 0.24 |
|                  | LES    | 2.21 ± 0.44         | 1.87 ± 0.34          |
|                  | MF     | 0.83 ± 0.17         | 0.71 ± 0.16          |
|                  | L4 lower endplate PS | ±             | ±                    |
|                  | LES    | 1.64 ± 0.39         | 1.44 ± 0.32          |
|                  | MF     | 1.08 ± 0.18         | 0.94 ± 0.20          |
|                  | L5 lower endplate PS | ±             | ±                    |
|                  | LES    | 0.90 ± 0.43         | 0.72 ± 0.30          |
|                  | MF     | 1.23 ± 0.21         | 1.02 ± 0.15          |
| Fat area         | L3 lower endplate cm² | 0.73 ± 0.45 | 0.91 ± 0.53 |
|                  | LES    | 3.26 ± 1.28         | 4.34 ± 2.13          |
|                  | MF     | 2.52 ± 1.16         | 3.52 ± 1.84          |
|                  | L4 lower endplate PS | ±             | ±                    |
|                  | LES    | 1.21 ± 0.80         | 1.54 ± 0.87          |
|                  | MF     | 3.65 ± 1.61         | 5.08 ± 2.46          |
|                  | L5 lower endplate PS | ±             | ±                    |
|                  | LES    | 3.56 ± 1.43         | 5.22 ± 3.05          |
|                  | MF     | 5.41 ± 1.87         | 7.19 ± 3.00          |
| Normalized fat CSA | L3 lower endplate | 0.05 ± 0.03 | 0.06 ± 0.03 |
|                  | LES    | 0.22 ± 0.09         | 0.29 ± 0.17          |
|                  | MF     | 0.16 ± 0.09         | 0.24 ± 0.16          |
|                  | L4 lower endplate PS | ±             | ±                    |
|                  | LES    | 0.27 ± 0.18         | 0.33 ± 0.19          |
|                  | MF     | 0.24 ± 0.12         | 0.35 ± 0.21          |
|                  | L5 lower endplate PS | ±             | ±                    |
|                  | LES    | 0.22 ± 0.09         | 0.37 ± 0.26          |
|                  | MF     | 0.35 ± 0.14         | 0.49 ± 0.25          |
Studies in nonoperative chronic LBP patients

Several studies have shown MF atrophy in chronic LBP patients [16-18,26]. Kader et al. visually analysed MRI images of LBP patients and reported MF atrophy in 80% of the patients [26]. The present imaging method is comparable to the one of Danneels et al., who compared chronic LBP patients with matched healthy subjects and found significant differences in muscle CSA only for the MF (limited to the L4 level), not for the PS and LES [17]. They therefore concluded that selective MF atrophy was present in chronic LBP [17]. In a study by Kamaz et al., muscle atrophy was especially prominent in the isolated MF, but also varying degrees of PA, quadratus lumborum and PS atrophy were found [11].

PS

The PS contained significantly more fat in the pain patients than in the asymptomatic subjects. However, the mCSA of the PS was not significantly different between the two groups. The present results suggest some PS deconditioning, without the presence of muscle atrophy. Previous data pertaining to PS size in postoperative patients have been conflicting. Mayer et al. found no significant difference in CSA of the PS in spinal surgery patients compared to controls without back pain [13]. In a study of predominantly surgical patients, Cooper et al. observed a significant decrease in muscle CSA of chronic LBP patients compared to acute LBP patients [12]. It is, however, unclear whether the results of the latter study applied to fat-free muscle CSA or total muscle CSA.

In the study by Kamaz et al., PS atrophy was documented in nonoperative chronic LBP patients [11]. Two studies of nonsurgical unilateral back pain compared CSA of the PS between the symptomatic and asymptomatic side. In nonsurgical LBP of at least 12 weeks’ duration, Barker et al. found evidence of coexisting PS and MF atrophy (in terms of total muscle CSA) [16]. Dangaria et al. reported a significant decrease in ipsilateral psaos major CSA (total muscle CSA) in the presence of LBP and disc herniation, but could not conclude whether this was due to atrophy at the sciatic side or to hypertrophy at the other side [27]. In contrast, Danneels et al. observed no significant difference in PS mCSA and fCSA between chronic LBP patients and healthy volunteers [17].

Level of operation

For none of the CSAs examined was the level of operation found to be a significant factor. Consequently, the operation did not seem to be responsible for the muscle atrophy observed. This finding is in accordance with the study by Sihvonen et al. In patients with poor recovery 2 to 5 years after surgery for spinal stenosis or disc herniation, they found muscle atrophy not to be restricted to the level of operation, but rather attributed it to muscle disuse [14]. Montesuneya et al. found back muscle atrophy to be present not only after posterior fusion, but also after anterior lumbar interbody fusion [18]. They concluded that besides direct surgical intervention, postoperative external fixation should also be held responsible for back muscle atrophy [18]. Also in this study, a weak positive correlation was documented between the atrophy ratio and the operating time only in posterior surgery, particularly nonfusion surgery. In a study by Kotilainen et al., the CSA of the lumbar muscles remained unchanged 6 months after microdiscectomy [28]. The authors attributed this to the tissue-sparing nature of the operation [28]. In the present study, MF deconditioning long after standard lumbar discectomy was not restricted to the level of operation, but was present on the 3 slices examined. In standard lumbar discectomy, the MF is only stripped off the spinous process and the vertebral arch at the level of operation. The exposure is minimal and the operating time is short, making muscle damage as the sole pain source in case of unsatisfactory results highly unlikely. However, the pain free patients had significantly more relief of back pain immediately postsurgery (p = 0.050), indicating that the cause of pain had been abolished during the operation. This was not entirely the case in the patients with persistent pain. The muscle abnormalities might therefore be the result and not the cause of their persistent pain. A more plausible explanation for MF atrophy at multiple levels and LES atrophy at the L3 level seems to be a pain-related inhibition phenomenon. Postoperative pain could have perpetuated the inhibition process that started at the occurrence of a symptomatic lumbar disc herniation. In the pain free patients, however, this was reversed by lumbar discectomy.

Because the TAMPA score for kinesiophobia was significantly higher in pain patients than in pain free patients, another hypothesis could be that back muscle deconditioning occurred as a consequence of fear avoidance in the patients with persistent pain. Back pain patients are more likely to avoid back extension movements than hip flexion movements, which explains why no atrophy was found for the mCSA of the PS. However, this muscle also showed signs of deconditioning as it contained more fat, which could be the result of some additive general muscle deconditioning in the pain patients.

Limitations of the study

Since there are no data for healthy controls in the current study design, CT muscle quality of the pain free discectomy patients could not be compared with that of healthy controls. Questions remain concerning the
presence of atrophy in pain free patients, which could for instance be influenced by the duration of pain preceding the disc surgery, or by back guarding to prevent recurrent LBP.

The clinical relevance of the differences between the pain group and the asymptomatic group still has to be proven in future studies.

A test-retest acquisition and consecutive measurements are necessary in order to estimate the reproducibility of the method. It was however not defendable to redo a 3D CT scan with 5000 Rad to this aim.

Conclusions
Comparison of CT muscle condition of the MF, LES and PS in lumbar discectomy patients with pain and without pain long after surgery showed a smaller fat free muscle CSA of the MF at all levels examined, a smaller fat free muscle CSA of the LES at the L3 level, and more fat in the PS muscle in pain patients. The level of operation was not found to be of importance. The present results suggest a general lumbar muscle dysfunction in the pain group, and in particular of the deep stabilizing muscle system.

Acknowledgements
The authors wish to thank the Fund for Scientific Research - Flanders, and all the patients who participated in the study.

Funding
Fund for Scientific Research - Flanders

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Authors’ contributions
KGWB participated in the study design, in collecting the data, the statistical analyses, and drafting of the manuscript. CT scan interpretation was performed by OV. VKS participated in collecting the data. PLC advised and assisted in the statistical analyses. CJI and DCC participated in the study design. GGV coordinated the study. LAD participated in the study design and in the progress and drafting of the manuscript. All authors read and approved the final manuscript.

Competing interests
The authors declare that they have no competing interests.

Received: 22 November 2010 Accepted: 31 March 2011
Published: 31 March 2011

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Pre-publication history
The pre-publication history for this paper can be accessed here:
http://www.biomedcentral.com/1471-2474/12/65/prepub

doi:10.1186/1471-2474-12-65
Cite this article as: Bouche et al.: Computed tomographic analysis of the quality of trunk muscles in asymptomatic and symptomatic lumbar discectomy patients. BMC Musculoskeletal Disorders 2011 12:65.