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General discussion

The present thesis concerns an in depth biomechanical analysis related to single level lumbar laminectomy. In orthopedic and neurosurgical practice, elderly patients often present with symptomatic degenerative lumbar spinal stenosis, which can be treated with a facet-sparing laminectomy. Post-operative symptomatic clinical instability, which is considered as a serious complication, justifies re-operation to stabilize and fuse the unstable segment [11]. Up to now, there are no clear criteria that define the need for additional instrumentation following a single level lumbar laminectomy. Although spinal stability increases after the application of posterior instrumentation, the procedure of stabilization itself increases the probability of implant-related complications, including adjacent segment degeneration (ASD). Moreover, it significantly increases the costs of patient care [9]. Furthermore, back pain and complaints related to spinal pathology are among the most common health problems and are associated with high healthcare costs and productivity losses [36]. Due to the ageing population, these costs can be expected to increase in the next decades.

This thesis is the first to provide a complete overview of human cadaveric spinal biomechanics before and after single level lumbar laminectomy in the aged lumbar spine and the biomechanical effects of additional posterior instrumentation. In case a single level lumbar laminectomy was biomechanically evaluated in literature, it usually considered an animal or finite element model [18, 35]. In addition, more extensive decompressive techniques were previously published [7, 8, 19, 26, 27], while adjacent segment instability was only investigated in a limited number of studies [5, 7]. Literature describing the biomechanical effects of adjacent segments after rigid posterior instrumentation is also scarce [5, 7].

As introduced in Chapter 1, this comprehensive biomechanical study using human lumbar spines considers the investigation of three main questions. *First.* How does single level laminectomy affect spinal ROM, stiffness and strength? *Secondly.* Can spinal instability following lumbar laminectomy be prognosticated based on clinically measurable imaging parameters? *Thirdly.* What are the biomechanical effects under submaximal loading conditions of single level laminectomy on the treated and adjacent levels with and without instrumentation of the treated segment?

To answer these main questions, a total of seven experimental sub questions were identified and studied in a similar number of studies (Chapters 2 – 8). Chapters 2 – 5 considered single level (L2 – L3 or L4 – L5) testing experiments until failure, while chapters 6 – 8 considered submaximal testing of the whole lumbar spine (L1 – L5). In the latter, stiffness was calculated around the neutral zone. All experimental studies were performed on custom-made testing machines by using fresh frozen human lumbar cadaveric spines, thereby enhancing the clinical relevance of our data. All seven study aims, as presented in the introduction, were met by these studies.

1. To assess the effects of single level lumbar laminectomy on shear biomechanics of the treated segment (Chapter 2).
2. To assess how shear biomechanics after single level lumbar laminectomy can be predicted (Chapter 3).
3. To assess the effects of single level lumbar laminectomy on torsion biomechanics of the treated segment (Chapter 4).
4. To assess how torsion biomechanics after single level lumbar laminectomy can be predicted (Chapter 5).
5. To assess the methodology for submaximal biomechanical testing of lumbar spinal segments (Chapter 6).
6. To quantify the effects of laminectomy on submaximal biomechanical behaviour of treated and adjacent lumbar segments (Chapter 7).
7. To quantify the effects of instrumented laminectomy on submaximal biomechanical behaviour of treated and adjacent lumbar segments (Chapter 8).

Shear biomechanics after laminectomy: effects and prediction on stability

The 2nd and 3rd chapter showed that laminectomy results in a decrease of shear force to failure (SFF) (44.2 %), shear displacement at failure (DF) (38.6 %) and shear stiffness (SS) (19.9 %). For segments with laminectomy, SS was significantly correlated with intervertebral disc degeneration and facet joint degeneration (Pfirrmann, Griffith, Lane and Pathria). Shear yield force (SYF) as a measure of the transition from elastic to plastic deformation, representing the first damage to a structure decreased 41.1 % after laminectomy and was correlated with intervertebral disc geometry (length, surface and volume), bone mineral content (BMC) and frontal area. SFF was correlated with disc length, BMC and bone mineral density (BMD). Using selections of the above-mentioned variables, SS, SYF and SFF could reasonably well to well be predicted for segments with laminectomy (r^2-values respectively: 0.53, 0.81 and 0.77). In conclusion, significant loss of strength and SS were predicted by DXA-derived measures of bone quantity and quality (respectively, BMC and BMD), intervertebral disc geometry and degenerative parameters, suggesting that low BMC or BMD, small intervertebral discs and absence of osteophytes could predict the possible development of postoperative shear instability following lumbar laminectomy.

Torsion biomechanics after laminectomy: effects and prediction on stability

In chapters 4 and 5 it was found that load–displacement curves have a typical bi-phasic pattern with a distinct early torsion stiffness (ETS) and late torsion stiffness (LTS). Following laminectomy, a significant and substantial decrease in ETS (34.1 %) and LTS (30.1 %) was found, whereas the torsion moment to failure (TMF) decreased to a lesser extent, with 17.6

%. Univariate analyses showed that a range of geometric characteristics and disc and bone quality parameters were also associated with torsion biomechanical properties of lumbar segments. Multivariate models showed that ETS, LTS and TMF could be predicted very well for segments after laminectomy (r^2-values 0.95, 0.87 and 0.93, respectively), with, just like for shear biomechanics, BMC and BMD being the main predictors. Furthermore, geometry parameters, i.e. intervertebral disc width, frontal area and facet joint tropism, were found to be predictors of ETS, LTS and TMF following laminectomy. In conclusion, as for shear biomechanics, vertebral bone content and geometry parameters can be used to predict the possible development of postoperative rotational instability following lumbar laminectomy.

Methodological assessment of submaximal testing of spinal biomechanics

The 6th chapter presents a methodological paper concerning the current gold standard in submaximal testing procedures for the lumbar spine in flexion-extension (FE), lateral bending (LB) and axial rotation (AR). It was found that the ROM increased slightly but significantly in all directions after three (FE: 1.0 %, LB: 1.5 %, and AR: 1.5 %) and after ten loading cycles (FE: 2.9 %, LB: 3.3 %, and AR: 3.3 %). Stiffness, measured around the neutral zone, was not significantly affected, but varied considerably over cycles. It was concluded that, although effects were small, assessment of the tenth cycle instead of the regularly used third cycle reduces viscoelastic effects in repeated measurements of ROM, because the spine is closer to a steady state condition. Furthermore, averaging over loading cycles would improve the assessment of stiffness estimates.

Effects of laminectomy on submaximal behaviour of treated and adjacent segments

Chapter 7 showed that, in submaximal testing, ROM at the level of laminectomy increased significantly after laminectomy for FE (7.3 %), LB (7.5 %), and AR (12.2 %). ROM of adjacent segments was not affected significantly, with exception of LB (– 7.7 %). Control segments were not affected. Spinal stiffness of treated, adjacent and control segments was not affected by laminectomy.

Effects of instrumented laminectomy on submaximal behaviour of treated and adjacent segments

In chapter 8, we found that ROM in AR increased (19.4 %) and stiffness decreased (– 18.0 %) significantly after laminectomy in treated segments, while FE and LB were not significantly affected. After laminectomy, ROM in AR of adjacent segments was also increased (11.0 %). Again FE and LB remained unaffected. Thus, as for chapter 7, laminectomy had limited effects on submaximal biomechanics of the treated and had only minor effects on adjacent segments. Instrumentation, however, significantly decreased ROM of treated segments in FE (– 74.3 %), LB (– 71.6 %) and AR (– 59.8 %). ROM of adjacent segments after instrumentation was only affected in LB, showing a decrease in ROM (– 12.9 %). Spinal stiffness of adjacent segments was not affected after instrumentation. In conclusion, while posterior instrumentation, as might be expected, substantially restricts spinal motion the treated segments, it does not result in increased range of motion or decreased stiffness of adjacent segments. Thus, spinal segments proximal to posterior fusion techniques do not seem to progress into unstable segments from an in vitro biomechanical point of view.

Clinical implications for laminectomy surgery

Our data implies that lumbar laminectomy increases the risk of developing a post-laminectomy syndrome during application of high loads, which could be present when performing demanding activities [13, 14, 15]. However, this risk might be assessed pre-operatively since we showed that multiple independent variables, together, largely determine the stiffness and failure strength of a lumbar spinal segment treated with a laminectomy. For both shear and torsion biomechanics, it was found that low vertebral bone content (BMC and BMD), small intervertebral discs, small bony structures, facet joint tropism and absence of osteophytes could predict the possible development of postoperative instability following lumbar laminectomy. For torsion, the decreasing effect of bone quality on spinal strength was even larger than the effects of laminectomy. This information can help to identify which patients are prone to develop a post-laminectomy syndrome and may therefore support or alter surgical decision-making, i.e. the decision whether or not to add additional posterior lumbar instrumentation in addition to a lumbar laminectomy. Some of the measures that we found to predict spinal (failure) biomechanics after lumbar laminectomy can be estimated based on standard pre-operative radiographs, CT- and MRI-imaging. However, standard pre-operative assessment for laminectomy does not include methods that provide the best predictive variables, i.e. DXA measurement to assess bone quality and to quantify bone density. Note that the high predictive value is despite the fact that DXA quantifies overall vertebral bone content rather than specifically for the neural arc. Subjects with low bone quality may require additional posterior instrumented stabilization to prevent postoperative instability. If parameters of bone quality are taken into consideration, often, BMD is used. However, we have also shown that geometry parameters are important for the estimation of post-operative spinal biomechanics. Therefore, especially BMC instead of BMD is a useful parameter since it integrates information on bone density and vertebral dimensions (BMC is defined as BMD (g/cm^2) multiplied by the total segmental surface area (FA) of the spinal segment (cm^2) and is expressed in grams, leading to the following equation: BMC (g) = BMD (g/cm^2) * FA (cm^2)). Besides the association between bone quality and shear and torsion biomechanics, also compression strength was previously correlated to BMC [2].

Clinical implications for additional posterior fusion surgery

The risk of developing a post-laminectomy syndrome, including postoperative pars interarticularis fractures, spondylolisthesis and development of degenerative scoliosis, seems quite substantial based on the results of this thesis. It may therefore be questioned whether patients can safely perform physically demanding tasks such as lifting heavy objects from low position after lumbar laminectomy since during these activities high load-levels are found in the lumbar area [13, 14, 15].

Taking this knowledge into consideration, it might be argued that all patients should be provided with posterior instrumentation after performing a laminectomy. However, in addition to well-known complications such as wound infection, the possibility of Adjacent Segment Disease (ASD) is receiving increasing interest among spine surgeons. It is progressively becoming clear that, in particular the use of rigid posterior lumbar interbody fusion (PLIF) and posterior lumbar fusion (PLF) as an addition to lumbar laminectomy holds a risk of ASD [28]. Purely pragmatic, typical topping-off procedures are used in some cases to prevent or slow down adjacent segment disease [20]. Topping-off procedures combine rigid fusion with a flexible pedicle screw system to prevent ASD [30]. During surgical planning, considerations regarding the use and type of posterior instrumentation would be better substantiated when post-operative biomechanical behaviour after laminectomy could be predicted. Currently, a decision whether or not to use additional instrumentation is based upon personal experience. Scientific sound criteria are needed. The current thesis provides biomechanical data that can be used to support such decision-making, as will be outlined in more detail below (Figure 1).

Recommendations and criteria for individual patients

Considering the pros and cons of posterior fusion and in order to provide a recommendation for the use of BMC in clinical practice, a decision making tree for the use of additional instrumentation after a single level lumbar laminectomy for degenerative spinal stenosis, in an individual patient is proposed in Figure 1.

One could argue that a safe strategy would be to focus at a predicted shear and rotational strength after laminectomy that is not lower than the lowest values in the untreated population. We found that shear force to failure (SFF) of untreated segments (5x L2 – L3 and 5x L4 – L5) ranged from 3284 – 909 N. After laminectomy SFF ranged from 1886 – 561 N. Out of ten segments, four segments did not reach a SFF after laminectomy larger than 909 N. Torsion moment to failure (TMF) of untreated segments (5x L2 – L3 and 5x L4 – L5) ranged from 79.2 – 27.8 Nm. After laminectomy TMF ranged from 72.2 – 23.7 N. Out of ten segments, three segments did not reach a TMF after laminectomy larger than 27.8 Nm. Considering corresponding BMC values, the above mentioned criterion would suggest spinal segments with a BMC < 20 grams should be instrumented. However, note that these data also imply that most segments would not require additional instrumentation after single level lumbar laminectomy.

Although we explanted lumbar spines before DXA measurements, leading to an underestimation of BMD and therefore BMC [31], these differences were only small. A definitive BMC cut-off point can be determined more accurately by conducting clinical studies in the future. We recommend assessing spinal BMC to predict clinically relevant instability in a prospective in vivo design to further enhance clinical applicability. In theory, a comparison between *in vivo* loading and predicted spinal strength could also lead to a clear criterion to decide whether or not a spinal segment progresses into an unstable segment and whether or not spinal instrumentation should be used. However, for this approach there are several issues that will need to be taken into consideration.

First, *in vivo* loading strongly depends on body weight, length and daily activities, which are all substantially affecting load levels. For shear biomechanics, estimations are inaccurate because it strongly depends on lumbar lordosis. Furthermore, estimations for shear loads strongly depend on segmental level. Shear loads are substantially higher at L5 – S1 than on more proximal situated levels. Therefore, to decide on the need for additional instrumentation the specific segment level should be taken into consideration. For rotation it is unknown what the load levels on segments is in an in vivo situation. Therefore, in addition to clinical studies, also *in vivo* work to assess load levels per person by adjusting for body-weight and length might strengthen a clinical applicable cut-off value for BMC and should therefore be further investigated.

Second, the use of a BMC-value to improve clinical practice means that all patients undergoing lumbar laminectomy should obtain a DXA-scan before surgery. This low-radiation scan will not only provide a surgeon with the necessary information on post-operative spinal biomechanics, it will also enable a surgeon to foresee possible complications with screw placement and in the long-term pull–out strength of pedicle screws. Pull-out strength of spinal implants is proved to be dependent on bone mineral quality as measured by dual X-ray absorptiometry (DXA) [34] and this dependency needs to be taken into account. Techniques to increase pull-out strength in osteoporotic patients such as screw augmentation are available and might be a solution for this specific problem [6].

Third, Macintosh and Bogduk elucidated on the biomechanical relevance of the lumbar multifidus muscles and attachments of the lumbar spinous erector muscle, including the longissimus and iliocostalis muscles [21, 22]. These local spinal muscles are crucial for stabilization of the spine. Basically, the lumbar spine is an instable construct, however, the co-activation of agonist and antagonist muscles increases spinal stability [27]. Due to a laminectomy, all spinal structures attached to the spinal process and part of the lamina are partially disrupted or completely disabled. The addition of spinal instrumentation possibly disrupts the muscular integrity even more. Unfortunately, we were not able to quantify this resultant instability following laminectomy. However, we do suggest that these alterations in *in vivo* muscle function might be crucial for instability and subsequent complications in the long-term, and should thus be investigated in future work.

In Figure 1, a suggested decision making algorithm combining anthropometry, behavioural demands and BMC as an aid to determine spinal stability after a single level lumbar laminectomy is presented. This algorithm can be used as a surgical decision making tool to determine whether or not to use additional instrumentation following single level lumbar laminectomy. At first, a patient is conservatively treated for degenerative lumbar spinal stenosis with the exception of patients with a cauda equina syndrome. In case conservative treatment fails, surgery such as a single level lumbar laminectomy is considered. During surgical planning, patients should have a DXA scan to determine the BMC of the affected spinal segment. In addition, patients should be assessed for criterion adaptation factor A (anthropometry) and factor B (behavioural demands). Since in vivo loading strongly depends on a patient's anthropometry, it might be argued that the initial BMC criterion should be multiplied by factor A. Factor A or body weight and height relative to the population average, could lead to three types of factors including an outcome < 1.0 or 1.0 or > 1.0. Depending on the discrepancy with the population average, the relative factor in- or decreases proportionally. Note that specifically of both body weight and body height increase load levels on the lumbar spine. Therefore, the Body Mass Index (BMI) would not be a suitable parameter. For behavioural demands, a categorical scale could be used. High demanding patients should be ascribed with a factor B > 1.0 while, normal demanding patients would be granted with a factor B = 1.0 and low demanding patients with a factor B < 1.0. Similar to factor A, proportionality of behavioural demands (Factor B) needs to be taken into consideration. Finally, according to the final BMC criterion a more informed choice could be made on the use of instrumentation. Note that this decision-making tree holds a preliminary recommendation. Further research should be conducted in order to, for example, define the effect of body weight and physical activity on in vivo loading of the human lumbar spine.

If in an individual case the use of spinal instrumentation is considered, its primary focus should be on re-stabilizing the level at which the laminectomy was performed, since we did not find substantial effects of single level lumbar laminectomy on adjacent segments in our submaximal test setup. We believe that, for deciding whether or not to add (multilevel) instrumentation after laminectomy, considerations with regard to failure loads are most important. Our reported effects of laminectomy on failure shear and torsion loads were substantially larger than effects of laminectomy on submaximal biomechanical parameters. Thus, considerations with regard to the question whether or not to apply posterior instrumentation, should be based on failure loads rather than on changes in range of motion and stiffness around the neutral orientation. However, in this thesis we have restricted our results to shear and torsion failure properties. While other motion direction might hold clinical relevance, we believe that shear and torsion loads are in general the most important loading mechanisms leading to spinal trauma.

We also found that posterior instrumentation does not change adjacent level biomechanics with exception of ROM in LB of the proximal levels. Based on our biomechanical results there is no reason for long constructs in single level lumbar laminectomy or the use of topping-off procedures proximally adjacent to rigid fusion. In light of topping-off procedures in addition to posterior fusion, we even advise to be cautious since preventive effects of these procedures on adjacent segment disease have not conclusively been proven. Hence, those procedures do increase the risk of implant related complications. Furthermore, the effects of topping-off procedures on the adjacent levels are unknown. When arguing for the use of topping-off procedures to slow down adjacent segment disease, there does not seem to be a biomechanical argument.

Finally, topping–off procedures perfectly illustrate current changes in spine surgery practice and in healthcare in general. In light of evidence based medicine (EBM) and health technology assessment (HTA), costs of healthcare interventions are increasingly considered important [36]. To be able to make well-informed decisions, it is of utmost importance to obtain valid and reliable information about safety, effectiveness and cost-effectiveness of interventions [36]. It is well known that the use of instrumentation alongside a laminectomy significantly increases the costs of this procedure [12, 16, 17]. In general it could be argued that the clinical advantages of an instrumented procedure should, considering the costs, be substantially better than non-instrumented laminectomy in order to be cost-effective.

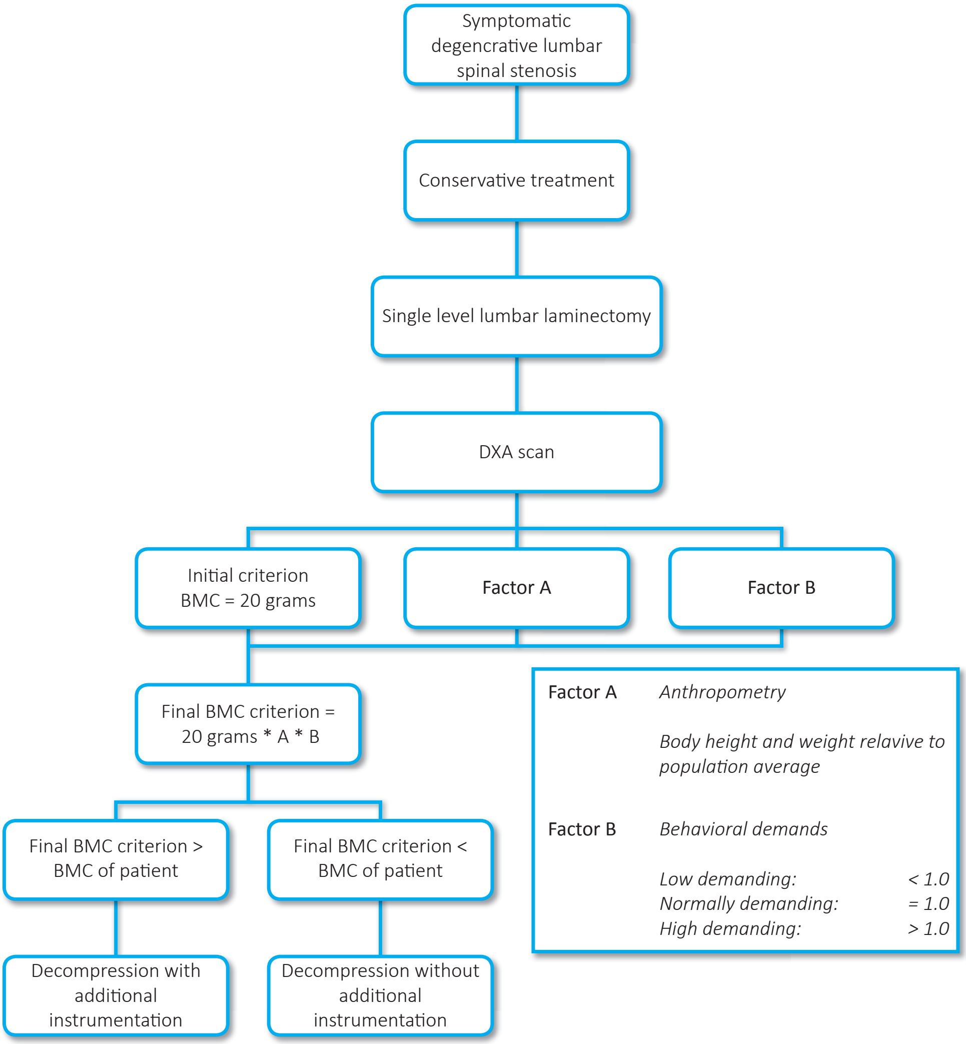

Figure 1. Suggested decision-making algorithm for lumbar laminectomy with or without instrumentation.

Limitations

From a biomechanical point of view, this thesis holds several limitations. We acknowledge that our results are mere in vitro biomechanical results and therefore only represent clinical value to certain extent. It is important to emphasize that translation from biomechanical studies to clinical practice is often difficult. However, in vitro evaluation of spinal biomechanics has been acknowledged as the golden standard for many years, especially when it comes to evaluation of surgical strategies and spinal implant development [37].

When comparing different biomechanical evaluations of the lumbar spine, uniformity of models is crucial in order to come to generalizable conclusions. However, often studies that investigated decompressive techniques and/or instrumentation of the lumbar spine reported substantially different outcomes. In most cases, differences in outcomes were probably caused by more extensive decompressive techniques or the use of follower loads. Another possible explanation was that different load-levels were used. In this thesis, when loading single spine segments, we selected a compression load of 1600 N during failure–testing (Chapters 2 – 5) because it is physiologically relevant [13, 14, 15] and allows for comparison with previous work [33, 35]. While this force may seem high, it is not very high compared to that estimated in vivo compression. Mainly due to muscle forces, the spine is already subjected to forces of this magnitude when the trunk is inclined about 45 degrees forward. In addition, this amount of preload is a compromise between applying compression forces that are sufficiently large to simulate spinal loads that occur in vivo when large shear forces are present [13, 14, 15, 32], but low enough to avoid damage due to compression forces alone [2]. During our submaximal experiments with complete lumbar spines (Chapters 6 – 9) we preloaded the spine with 250 N for 1 hour, which is obviously relatively low in contrast to physiological loading [1]. Preloading with 250 N was chosen, since buckling might occur when loading a complete lumbar spine with a higher load [25]. We did not apply axial loading during testing, again to prevent buckling. While so-called follower loads would allow for axial loading during bending without buckling, such loads inevitably cause additional moments of unknown magnitude, which would interfere with the purpose of this thesis. Since we tested spines of elderly cadavers, which could be osteoporotic, we decided to use a 4 Nm load level. It was recommended to decrease standard pure moments of 7.5 Nm by 50 % when testing osteoporotic spines [37]. Comparable load levels were previously used [3, 4, 10].

In this thesis we defined spinal instability from a biomechanical perspective as a significant and substantial increase in range of motion (ROM), and/or reduced stiffness (around the neutral zone [23, 24] in submaximal testing experiments) and/or a decrease in ultimate spinal strength. In addition, we have added yielding or a derivative of yielding (i.e. early torsion stiffness versus late torsion stiffness) to these commonly used biomechanical parameters in our biomechanical evaluations (Chapters 3 – 5). The yield point might be one of the most critical biomechanical properties, because it marks the beginning of the irreversible deformation of a spinal motion segment, signaling the appearance of the soft tissue and / or trabecular bone lesions [29]. We expect that when load levels cross the yield point, sub-clinical damage will occur. Such damage may, at a later stage, lead to symptoms. Unfortunately, we were not able to exactly calculate the yield point in torsion testing. Therefore we argued that the yield point was within the transition zone between ETS and LTS. Obviously, a yield point was not defined during submaximal testing experiments.

Another limitation regarding the use of posterior instrumentation is that we did not investigate PLIF, TLIF and XLIF techniques. Replacement of the intervertebral disc by interbody devices, such as a cage, might lead to different biomechanical outcomes. We cannot draw conclusions on this matter and recommend a new biomechanical study to evaluate these effects.

Conclusions

In conclusion, single level facet sparing lumbar laminectomy destabilizes the spine. To put these biomechanical alterations in clinical perspective is a challenge. However, we found that a pre-operative DXA scan to quantify BMC provides a surgeon with a practical tool to prognosticate which spinal segments have a high risk of developing into an unstable one after performing a single level lumbar laminectomy. In most cases instrumentation as an additive to single level lumbar laminectomy will prove not be necessary because residual spinal stability will fall within our proposed criteria. In case it is decided to use additional instrumentation then our study results show that it is sufficient to stabilize the decompressed segment only. A laminectomy does not seem to alter the biomechanical behavior of the adjacent segment, however the possible role of post-operative muscle function should thereby be considered and requires further evaluation in future research. Furthermore, in a situation in which a single level lumbar laminectomy is instrumented, there does not seem to be a substantial alteration in the biomechanical behavior of the adjacent level. Based on these results, it could be argued that, in case of a single level decompression with additional instrumentation there is no need to extent the spondylodeses with rigid or topping-off dynamic instrumentation techniques.

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