Sökning i databaser för vetenskaplig evidens: Diskproteskirurgi i ländryggen

Frågeställning

Vilken vetenskaplig evidens finns för effekt (livskvalitet, smärta och arbetsförmåga) och kostnadseffektivitet vid användning av diskproteskirurgi jämfört med steloperation vid smärta i ländryggen.

Bakgrund

Ländryggssmärta är ett stort medicinskt problem. Kirurgisk behandling vid kronisk ryggsmärta är vedertagen vid diskbråck, spinal stenos och spondylolistes. Kirurgisk behandling vid kronisk ländryggssmärta är mer kontroversiell. Den gängse metoden innebär steloperation av det smärtgivande ryggsegmentet.

En alternativ behandlingsmetod är operation med diskprotes. Denna metod bevarar rörligheten och har använts i begränsad omfattning i Sverige under de senaste 15 åren. I utvalda fall anses diskprotes vara effektivare än steloperation. Den har visat sig ge en snabbare och bättre smärtreduktion.

Diskprotes har använts i liten skala i SÖ sjukvårdsregionen, vid ryggkliniken, US med 5-10 patienter opererade under de senaste åren. Patienter som behöver opereras på flera nivåer eller som har komplicerande faktorer har remitterats till Stockholm Spine Center där Dr Svante Berg har stor erfarenhet av metoden och även utvärderat den genom avhandlingsarbete, bl a i år publicerat 5-årsresultat av en randomiserad och kontrollerad studie där diskprotes och steloperation jämförts (Skold, Tropp et al. 2013).

Metodrådets sammanfattande bedömning

Steloperation av delar av kotpelaren i ländryggen har under det senaste seklet blivit vanlig operation vid t ex skador, men även vid smärtor förorsakade av slitage och degeneration i kotpelare och diskar. Diskproteskirurgi som ersätter skadad disk eller diskar och därmed bevarar rörligheten i kotpelaren har prövats sedan slutet av 1980- talet.

Det finns i dagsläget otillräcklig evidens avseende långtidsresultat för att generellt ersätta steloperationer med diskprotes. Det finns dock evidens för att behandla selekterande patienter med diskprotes t ex när bevarande av rörligheten i korsryggen och smärtfrihet är av speciell betydelse. Totalkostnaden för sjukvården och samhället för diskprotes jämfört med steloperation är jämförbar eller lägre.

Sökning i HTA (Health Technology Assessment) databaser (2012-08-12)

*SBU - Kunskapscentrum för hälso- och sjukvård*en http://www.sbu.se/sv/

Ingen träff på ”diskproteskirurgi”

Socialstyrelsen – nationella riktlinjer
http://www.socialstyrelsen.se/riktlinjer/nationellariktlinjer

Ingen träff på ”diskproteskirurgi”

TRIP databasen http://www.tripdatabase.com/search/advanced

293 resultat på ”disc prosthesis”, varav 61 kontrollerade kliniska försök, 19 systematiska översikter och 11 evidensbaserade sammanfattningar. Drygt hälften rör primärt halsryggen.

År 2011: Review of Interim Funded Service: Artificial Intervertebral Disc Replacement – Lumbar. HTA analys på 170 sidor från Australien (MSAC 2011). Slutsatsen är att protesoperation i ländryggen på kort och mellanlång sikt är säker i genomförande, minskar smärta, framgångsrik i att återfå patienter i arbete, leder till patienttillfredsställelse, livskvalitet och bibehållna sexualfunktioner på motsvarande sätt som steloperation. Protesoperationen innebär 6,5 % lägre totalkostnader än steloperation.

År 2010: van den Eerenbeemt, K. D., R. W. Ostelo, et al. (2010). "Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **19**(8): 1262-1280. (van den Eerenbeemt, Ostelo et al. 2010) granskade vetenskapliga evidensen 1973 till 2008 med slutsatsen att det finns otillräcklig evidens för att generellt ersätta steloperation med protesoperation vid smärtor i ländryggen, speciellt p.g.a. osäkerhet kring slutresultat och patientsäkerhet över lång tid.

Det finns ytterligare två HTA-rapporter (NSH- National Institute for Health Research) från 2003 respektive 2004 med liknande slutsatser som ovan.

*The Cochrane Lib*rary http://www.thecochranelibrary.com/view/0/index.html

En träff på ”disc prosthesis”

År 2012: Boselie, T. F., P. C. Willems, et al. (2012). "Arthroplasty versus fusion in single-level cervical degenerative disc disease." The Cochrane database of systematic reviews **9**: CD009173 (Boselie, Willems et al. 2012) även sammanfattad i (Boselie, Willems et al. 2013).

Nio studier totalt inkluderande 2400 patienter med degenerativa sjukdomar i *halsryggens* diskar ingick i den jämförande granskningen av steloperation vs diskproteskirurgi avseende smärta och funktion. Åtta av studierna var industrisponsrade. Uppföljningstiden var 2 år.

Det fanns ingen kliniskt viktig skillnad mellan steloperation och disproteskirurgi avseende varken smärta eller funktion. En viss statistisk skillnad till fördel för steloperation påvisades dock avseende både smärta och funktionalitet. Författarna påpekade behovet av längre uppföljningstider, gärna 5 år.

Denna viktiga metaanalys gäller halsryggen och inte ländryggen – som är huvudfrågeställningen här.

Clinical Evidence http://www.clinicalevidence.com/x/index.html

Ingen träff på ”disc prosthesis”.

International Network of Agencies for Health Technology Assessment http://www.inahta.net/

91 träffar på ”disc prosthesis” varav 14 handlade om sjukdomskategorin ”Musculoskeletal diseases”, men ingen specifikt om aktuella frågeställning.

Nasjonalt kunnskapssenter for helsetjenesten, Norge http://www.kunnskapssenteret.no/

Inga träffar på ”diskproteskirurgi”

Annan vetenskaplig evidens

I PubMed finns i skrivande stund 189 vetenskapliga artiklar när man söker på ”total disc replacement”, varav flera handlar om halsryggen.

Freeman och Davenports systematiska översikt från 2006 (Freeman and Davenport 2006) som inkluderade två randomiserade och kontrollerade studier, andra studier och översikter drog slutsatsen att evidens saknas för att behandling med protes är bättre än steloperation i ländryggen.

I en metaanalys ”av Cochrane- typ” som granskade alla randomiserade och kontrollerade studier på steloperation vs protesoperation på ländryggen fram till juni 2009 fann Jajun et al. (Yajun, Yue et al. 2010) fem kontrollerade och randomiserade studier, inkluderande totalt 837 patienter. En av dessa fem studier som kompletterade med ”BAK cage interfusion” (fixering av ryggkotorna med verktyg) visade en klar fördel avseende smärta och funktion vid protesoperationen. Denna fördel kunde inte visas i övriga 4 studier varken efter 2 eller 5 års observationstid. Förekomsten av komplikationer och re-operationer i dessa 4 studier var också jämförbar både efter två och fem år.

Svante Berg försvarade 2010 en avhandling med titeln ”On total disc replacement” (Berg 2011). I en prospektiv, randomiserad och kontrollerad studie (Swedish Lumbar Spine Study) följde han och medarbetare 152 patienter behandlade med steloperation (72) respektive disproteskirurgi (80) i ländryggen (Berg, Tullberg et al. 2009). Vid två-års uppföljning var 30 % av patienterna i disprotesgruppen helt smärtfria jämfört med 15 % i stelopererade gruppen. Resultaten avseende andra parametrar var lika avseende andra parametrar än fullsmärtfrihet efter 2 år (Berg, Tullberg et al. 2009).

Vid 5-års uppföljning var 38 % av patienterna i disprotesgruppen helt smärtfria jämfört med 15 % i stelopererade gruppen (Skold, Tropp et al. 2013). Patienterna i disprotesgruppen hade generellt mindre smärta och mer påtaglig minskning av smärtan än i steloperationsgruppen.

En delstudie inom ” Swedish Lumbar Spine Study ” av kostnadseffektiviteten av steloperation respektive disproteskirurgi för 152 patienter (Fritzell, Berg et al. 2011) påvisades ingen statistisk skillnad mellan grupperna i totalkostnad för samhället, men sjukvårdskostnaderna var högre för steloperationen främst p.g.a. kostnader för förnyad operation för att ta bort material som användes för steloperationen.

Metodrådet i Sydöstra sjukvårdsregionen den 16 september 2013

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Landstinget i Jönköpings län

Petra Lindberg, förvaltningsdirektör

Raymond Lenrick, utvecklingsledare/överläkare

Landstinget i Kalmar län

Åke Aldman, chefläkare

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Litteraturreferenser

Berg, S. (2011). "On total disc replacement." Acta orthopaedica. Supplementum **82**(343): 1-29.

Low back pain consumes a large part of the community's resources dedicated to health care and sick leave. Back disorders also negatively affect the individual leading to pain suffering, decreased quality-of-life and disability. Chronic low back pain (CLBP) due to degenerative disc disease (DDD) is today often treated with fusion when conservative treatment has failed and symptoms are severe. This treatment is as successful as arthroplasty is for hip arthritis in restoring the patient's quality of life and reducing disability. Even so, there are some problems with this treatment, one of these being recurrent CLBP from an adjacent segment (ASD) after primarily successful surgery. This has led to the development of alternative surgical treatments and devices that maintain or restore mobility, in order to reduce the risk for ASD. Of these new devices, the most frequently used are the disc prostheses used in Total Disc Replacement (TDR). This thesis is based on four studies comparing total disc replacement with posterior fusion. The studies are all based on a material of 152 patients with DDD in one or two segments, aged 20-55 years that were randomly treated with either posterior fusion or TDR. The first study concerned clinical outcome and complications. Follow-up was 100% at both one and two years. It revealed that both treatment groups had a clear benefit from treatment and that patients with TDR were better in almost all outcome scores at one-year follow-up. Fusion patients continued to improve during the second year. At two-year follow-up there was a remaining difference in favour of TDR for back pain. 73% in the TDR group and 63% in the fusion group were much better or totally pain-free (n.s.), while twice as many patients in the TDR group were totally pain free (30%) compared to the fusion group (15%). Time of surgery and total time in hospital were shorter in the TDR group. There was no difference in complications and reoperations, except that seventeen of the patients in the fusion group were re-operated for removal of their implants. The second study concerned sex life and sexual function. TDR is performed via an anterior approach, an approach that has been used for a long time for various procedures on the lumbar spine. A frequent complication reported in males when this approach is used is

persistent retrograde ejaculation. The TDR group in this material was operated via an extra-peritoneal approach to the retroperitoneal space, and there were no cases of persistent retrograde ejaculation. There was a surprisingly high frequency of men in the fusion group reporting deterioration in ability to have an orgasm postoperatively. Preoperative sex life was severely hampered in the majority of patients in the entire material, but sex life underwent a marked improvement in both treatment groups by the two-year follow-up that correlated with reduction in back pain. The third study was on mobility in the lumbar spinal segments, where X-rays were taken in full extension and flexion prior to surgery and at two-year follow-up. Analysis of the films showed that 78% of the patients in the fusion group reached the surgical goal (non-mobility) and that 89% of the TDR patients maintained mobility. Preoperative disc height was lower than in a normative database in both groups, and remained lower in the fusion group, while it became higher in the TDR group. Mobility in the operated segment increased in the TDR group postoperatively. Mobility at the rest of the lumbar spine increased in both treatment groups. Mobility in adjacent segments was within the norm postoperatively, but slightly larger in the fusion group. In the fourth study the health economics of TDR vs Fusion was analysed. The hospital costs for the procedure were higher for patients in the fusion group compared to the TDR group, and the TDR patients were on sick-leave two months less. In all, these studies showed that the results in the TDR group were as good as in the fusion group. Patients are more likely to be totally pain-free when treated with TDR compared to fusion. Treatment with this new procedure seems justified in selected patients at least in the short-term perspective. Long-term follow-up is underway and results will be published in due course.

Berg, S., T. Tullberg, et al. (2009). "Total disc replacement compared to lumbar fusion: a randomised controlled trial with 2-year follow-up." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **18**(10): 1512-1519.

The study design includes a prospective, randomised controlled study comparing total disc replacement (TDR) with posterior fusion. The main objective of this study is to compare TDR with lumbar spinal fusion, in terms of clinical outcome, in patients referred to a spine clinic for surgical evaluation. Fusion is effective for treating chronic low back pain (LBP), but has drawbacks, such as stiffness and possibly adjacent level degradation. Motion-preserving options have emerged, of which TDR is frequently used because of these drawbacks. How the results of TDR compare to fusion, however, is uncertain. One hundred and fifty-two patients with a mean age of 40 years (21-55) were included: 90 were women, and 80 underwent TDR. The patients had not responded to a conservative treatment programme and suffered from predominantly LBP, with varying degrees of leg pain. Diagnosis was based on clinical examination, radiographs, MRI, and in unclear cases, diagnostic injections. Outcome measures were global assessment (GA), VAS for back and leg pain, Oswestry Disability Index, SF36 and EQ5D at 1 and 2 years. Follow-up rate was 100%, at both 1 and 2 years. All outcome variables improved in both groups between preoperative and follow-up assessment. The primary outcome measure, GA, revealed that 30% in

the TDR group and 15% in the fusion group were totally pain-free at 2 years (P = 0.031). TDR patients had reached maximum recovery in virtually all variables at 1 year, with significant differences compared to the fusion group. The fusion patients continued to improve and at 2 years had results similar to TDR patients apart from numbers of pain-free. Complications and reoperations were similar in both groups, but pedicle screw removal as additive surgery, was frequent in the fusion group. One year after surgery, TDR was superior to spinal fusion in clinical outcome, but this difference had diminished by 2 years, apart from (VAS for back pain and) numbers of pain-free. The long-term benefits have yet to be examined.

Boselie, T. F., P. C. Willems, et al. (2012). "Arthroplasty versus fusion in single-level cervical degenerative disc disease." The Cochrane database of systematic reviews **9**: CD009173.

BACKGROUND: There is ongoing debate about whether fusion or arthroplasty is superior in the treatment of single level cervical degenerative disc disease. Mainly because the intended advantage of arthroplasty over fusion, that is, the prevention of symptoms due to adjacent segment degeneration in the long term, is not confirmed yet. Until sufficient long-term results become available, it is important to know whether results of one of the two treatments are superior to the other in the first one to two years. OBJECTIVES: To assess the effects of arthroplasty versus fusion for radiculopathy or myelopathy, or both due to single level cervical degenerative disc disease. SEARCH METHODS: We searched the following databases for randomised controlled trials (RCTs): CENTRAL (The Cochrane Library 2011, Issue 2), MEDLINE, EMBASE, and EBMR. Additionally, we searched the System for Information on Grey Literature (SIGLE), subheading Biological and Medical Sciences, the US Food and Drug Administration (FDA) database on medical devices, and Clinicaltrials.gov to identify trials in progress. We also screened the reference list of all selected papers. Date of search: 25 May 2011. SELECTION CRITERIA: We included RCTs that directly compared any type of cervical fusion with any type of arthroplasty, with at least one year of follow-up. Primary outcomes were arm pain, neck pain, neck-related functional status, patient satisfaction, neurological outcome, and global health status. Secondary outcomes were the presence of (radiological) fusion, revision surgery at the treated level, secondary surgery on adjacent levels, segmental mobility of treated and adjacent levels, and work status. DATA COLLECTION AND ANALYSIS: Study selection was performed independently by three review authors, and 'Risk of bias' assessment and data extraction were performed by two review authors. In case of missing data or insufficient information for a judgement about risk of bias, we tried to contact the study authors or the study sponsor. The data were entered into RevMan by one review author and subsequently checked by a second review author. We assessed the quality of evidence using GRADE. We analysed heterogeneity and performed sensitivity analyses for the pooled analyses. MAIN RESULTS: We included nine studies (2400 participants), five of which had a low risk of bias. Eight of these studies were industry sponsored. The most important results showed low-quality evidence for a small but significant difference in alleviation of arm pain at one to two years in favour of arthroplasty (mean difference (MD) -1.54; 95% confidence interval (CI) -2.86 to -0.22; 100-point scale). A small

study effect could not be ruled out for this outcome in the sensitivity analyses. This means that smaller studies (or small published subsets of larger studies) showed larger differences for this outcome, which may indicate publication bias. Also, moderate-quality evidence showed a small difference in neck-related functional status at one to two years in favour of arthroplasty (MD -2.79; 95% CI -4.73 to -0.85; 100-point scale) and a small difference in neurological outcome in favour of arthroplasty (risk ratio (RR) 1.05; 95% CI 1.01 to 1.09). These two outcomes were robust to sensitivity analyses. For none of the primary outcomes, was a clinically relevant difference shown. Additionally, there was high-quality evidence for a large, statistically significant difference in segmental mobility at one to two years (measured as degrees segmental range of motion) at the treated level (MD 6.90; 95% CI 5.45 to 8.35). There was low-quality evidence that there was no statistically significant difference in secondary surgery at the adjacent levels at one to two years (RR 0.60; 95% CI 0.35 to 1.02). The latter was not robust to sensitivity analyses. AUTHORS' CONCLUSIONS: There was a tendency for clinical results to be in favour of arthroplasty; often these were statistically significant. However, differences in effect size were invariably small and not clinically relevant for all primary outcomes. Significance was often gained or lost in the varying sensitivity analyses, probably owing to the relatively small number of studies, in combination with the small differences that were found. Given the fact that all of the included studies were not blinded, this could be due to patient or carer expectations. However, at this time both treatments can be seen as valid options with respect to results at a maximum of one to two years. Given the current absence of truly long-term results, use of these mobile disc prostheses should still be limited to clinical trials. There was high-quality evidence that the goal of preservation of segmental mobility in arthroplasty was met. A statistically significant effect on the incidence of secondary symptoms at adjacent levels, the primary goal of arthroplasty over fusion, was not found at one to two years. If there was a protective effect, this should become clearer over time. A future update, when studies with 'truly long-term' results (five years or more) become available, should focus on this issue.

Boselie, T. F., P. C. Willems, et al. (2013). "Arthroplasty versus fusion in single-level cervical degenerative disc disease: a cochrane review." Spine **38**(17): E1096-1107.

STUDY DESIGN: A systematic review of randomized controlled trials (RCTs). OBJECTIVE: To assess the effects of arthroplasty versus fusion in the treatment of radiculopathy or myelopathy, or both, due to single-level cervical degenerative disc disease. SUMMARY OF BACKGROUND DATA: There is ongoing debate about whether fusion or arthroplasty is superior in the treatment of single-level cervical degenerative disc disease. Mainly because the intended advantage of arthroplasty compared with fusion, prevention of symptoms due to adjacent segment degeneration in the long term, is not confirmed yet. Until sufficient long-term results become available, it is important to know whether results of 1 of the 2 treatments are superior to the other in the first 1 to 2 years. METHODS: We searched electronic databases for randomized controlled trials. We included randomized controlled trials that directly compared any type of cervical fusion with any type of cervical arthroplasty, with at least 1 year of follow-up. Study selection was performed independently by 3 review

authors, and "risk of bias" assessment and data extraction were independently performed by 2 review authors. In case of missing data, we contacted the study authors or the study sponsor. We assessed the quality of evidence. RESULTS: Nine studies (2400 participants) were included in this review; 5 of these studies had a low risk of bias. Results for the arthroplasty group were better than the fusion group for all primary comparisons, often statistically significant. For none of the primary outcomes was a clinically relevant difference in effect size shown. Quality of the evidence was low to moderate. CONCLUSION: There is low to moderate quality evidence that results are consistently in favor of arthroplasty, often statistically significant. However, differences in effect size were invariably small and not clinically relevant for all primary outcomes.Level of Evidence: 1.

Freeman, B. J. and J. Davenport (2006). "Total disc replacement in the lumbar spine: a systematic review of the literature." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **15 Suppl 3**: S439-447.

The current evidence for total disc replacement was assessed by performing a systematic review of the published literature. This search identified two randomised controlled trials (RCTs), two previous systematic reviews, seven prospective cohort studies, eleven retrospective cohort studies and eight case series. The RCTs involved the use of the Charite artificial disc and the Pro-Disc II total disc replacement. All papers analysed were classified according to their level of evidence as defined by the Centre for Evidence Based Medicine, Oxford, UK (www.cebm). For degenerative disc disease at L4/5 or L5/S1, both the clinical outcome and the incidence of major neurological complications following insertion of the Charite artificial disc were found to be equivalent to those observed following a single level anterior lumbar interbody fusion 2 years following surgery. However, only 57% of patients undergoing total disc replacement and 46% of patients undergoing arthrodesis met the four criteria listed for success. The range of flexion/extension was restored and maintained with the Charite artificial disc. The role for two or three level disc replacement in the treatment of degenerative disc disease remains unproven. To date, no study has shown total disc replacement to be superior to spinal fusion in terms of clinical outcome. The long-term benefits of total disc replacement in preventing adjacent level disc degeneration have yet to be realised. Complications of total disc replacement may not be known for many years. There are numerous types of disc prostheses and designs under study or in development. Well designed prospective RCTs are needed before approval and widespread application of this technology.

Fritzell, P., S. Berg, et al. (2011). "Cost effectiveness of disc prosthesis versus lumbar fusion in patients with chronic low back pain: randomized controlled trial with 2-year follow-up." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **20**(7): 1001-1011.

This randomized controlled health economic study assesses the cost-effectiveness of the concept of total disc replacement (TDR) (Charite/Prodisc/Maverick) when compared with the concept of instrumented lumbar fusion (FUS) [posterior lumbar fusion (PLF) /posterior lumbar interbody fusion (PLIF)]. Social and healthcare perspectives after 2 years are reported. In all, 152 patients were randomized to either TDR (n = 80) or lumbar FUS (n = 72). Cost to society (total mean cost/patient, Swedish kronor = SEK, standard deviation) for TDR was SEK 599,560 (400,272), and for lumbar FUS SEK 685,919 (422,903) (ns). The difference was not significant: SEK 86,359 (-45,605 to 214,332). TDR was significantly less costly from a healthcare perspective, SEK 22,996 (1,202 to 43,055). Number of days on sick leave among those who returned to work was 185 (146) in the TDR group, and 252 (189) in the FUS group (ns). Using EQ-5D, the total gain in quality adjusted life years (QALYs) over 2 years was 0.41 units for TDR and 0.40 units for FUS (ns). Based on EQ-5D, the incremental cost-effectiveness ratio (ICER) of using TDR instead of FUS was difficult to analyze due to the "non-difference" in treatment outcome, which is why cost/QALY was not meaningful to define. Using cost-effectiveness probabilistic analysis, the net benefit (with CI) was found to be SEK 91,359 (-73,643 to 249,114) (ns). We used the currency of 2006 where 1 EURO = 9.26 SEK and 1 USD = 7.38 SEK. It was not possible to state whether TDR or FUS is more cost-effective after 2 years. Since disc replacement and lumbar fusion are based on different conceptual approaches, it is important to follow these results over time.

MSAC (2011). Review of Interim Funded Service: Artificial Intervertebral Disc Replacement - Lumbar. Camberra, Medical Service Advisory Committee (MSAC)**:** 1-170.

Skold, C., H. Tropp, et al. (2013). "Five-year follow-up of total disc replacement compared to fusion: a randomized controlled trial." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society.

PURPOSE: To evaluate long-term clinical results of lumbar total disc replacement (TDR) compared with posterior lumbar fusion. METHODS: This prospective randomized controlled trial comprised 152 patients; 80 were randomized to TDR and 72 to fusion. All patients had chronic low back pain (CLBP) and had not responded to nonsurgical treatment. Primary outcome measure was global assessment of back pain (GA), secondary outcome measures were back and leg pain, Oswestry Disability Index (ODI), EQ5D, and SF-36. All measures were collected from SweSpine (Swedish national register for spinal surgery) at 1, 2, and 5 years. Follow-up rate at 5 years was 99.3 %. RESULTS: Both groups showed clinical improvement at 5-year follow-up. For GA, 38 % (30/80) in the TDR group were totally pain free vs. 15 % (11/71) in the fusion group ($p < 0.003$). Back pain and improvement of back pain were better in the TDR group: VAS back pain at 5 years 23 +/- 29 vs. 31 +/- 27, $p = 0.009$, and VAS improvement of back pain at 5 years 40 +/- 32 vs. 28 +/- 32, $p = 0.022$. ODI and improvement in ODI were also better in the TDR group: ODI at 5 years 17 +/- 19 vs. 23 + 17, $p = 0.02$ and ODI improvement at 5 years 25 +/- 18 vs. 18 +/- 19 ($p = 0.02$). There was no difference in complications and reoperations between the two

groups. CONCLUSIONS: Global assessment of low back pain differed between the two surgical groups at all follow-up occasions. Significant differences between groups concerning back pain, pain improvement, and ODI were present at 1 year and disappeared at 2 years, but reappeared at the 5-year follow-up.

van den Eerenbeemt, K. D., R. W. Ostelo, et al. (2010). "Total disc replacement surgery for symptomatic degenerative lumbar disc disease: a systematic review of the literature." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **19**(8): 1262-1280.

The objective of this study is to evaluate the effectiveness and safety of total disc replacement surgery compared with spinal fusion in patients with symptomatic lumbar disc degeneration. Low back pain (LBP), a major health problem in Western countries, can be caused by a variety of pathologies, one of which is degenerative disc disease (DDD). When conservative treatment fails, surgery might be considered. For a long time, lumbar fusion has been the "gold standard" of surgical treatment for DDD. Total disc replacement (TDR) has increased in popularity as an alternative for lumbar fusion. A comprehensive systematic literature search was performed up to October 2008. Two reviewers independently checked all retrieved titles and abstracts, and relevant full text articles for inclusion. Two reviewers independently assessed the risk of bias of included studies and extracted relevant data and outcomes. Three randomized controlled trials and 16 prospective cohort studies were identified. In all three trials, the total disc replacement was compared with lumbar fusion techniques. The Charite trial (designed as a non-inferiority trail) was considered to have a low risk of bias for the 2-year follow up, but a high risk of bias for the 5-year follow up. The Charite artificial disc was non-inferior to the BAK Interbody Fusion System on a composite outcome of "clinical success" (57.1 vs. 46.5%, for the 2-year follow up; 57.8 vs. 51.2% for the 5-year follow up). There were no statistically significant differences in mean pain and physical function scores. The Prodisc artificial disc (also designed as a non-inferiority trail) was found to be statistically significant more effective when compared with the lumbar circumferential fusion on the composite outcome of "clinical success" (53.4 vs. 40.8%), but the risk of bias of this study was high. Moreover, there were no statistically significant differences in mean pain and physical function scores. The Flexicore trial, with a high risk of bias, found no clinical relevant differences on pain and physical function when compared with circumferential spinal fusion at 2-year follow up. Because these are preliminary results, in addition to the high risk of bias, no conclusions can be drawn based on this study. In general, these results suggest that no clinical relevant differences between the total disc replacement and fusion techniques. The overall success rates in both treatment groups were small. Complications related to the surgical approach ranged from 2.1 to 18.7%, prosthesis related complications from 2.0 to 39.3%, treatment related complications from 1.9 to 62.0% and general complications from 1.0 to 14.0%. Reoperation at the index level was reported in 1.0 to 28.6% of the patients. In the three trials published, overall complication rates ranged from 7.3 to 29.1% in the TDR group and from 6.3 to 50.2% in the fusion group. The overall reoperation rate at

index-level ranged from 3.7 to 11.4% in the TDR group and from 5.4 to 26.1% in the fusion group. In conclusion, there is low quality evidence that the Charite is non-inferior to the BAK cage at the 2-year follow up on the primary outcome measures. For the 5-year follow up, the same conclusion is supported only by very low quality evidence. For the ProDisc, there is very low quality evidence for contradictory results on the primary outcome measures when compared with anterior lumbar circumferential fusion. High quality randomized controlled trials with relevant control group and long-term follow-up is needed to evaluate the effectiveness and safety of TDR.

Yajun, W., Z. Yue, et al. (2010). "A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease." European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society **19**(8): 1250-1261.

Lumbar fusion has been developed for several decades and became the standard surgical treatment for symptomatic lumbar degenerative disc disease (DDD). Artificial total disc replacement (TDR), as an alternative for spinal arthrodesis, is becoming more commonly employed treating lumbar DDD. It is still uncertain whether TDR is more effective and safer than lumbar fusion. To systematically compare the effectiveness and safety of TDR to that of the fusion for the treatment of lumbar DDD, we performed a meta-analysis. Cochrane review methods were used to analyze all relevant randomized controlled trials published up to July 2009. Five relevant randomized controlled trials involving 837 patients were identified. Patients in TDR group have slightly better functioning and less back or leg pain without clinical significance, and significantly higher satisfaction status in TDR group compared with lumbar fusion group at the 2-year follow-up. But these outcomes are highly influenced by the study with BAK cage interbody fusion, the function/pain and patient satisfaction status are no longer significantly different between two groups after excluding this study. At 5 years, these outcomes are not significantly different between comparing groups. The complication and reoperation rate of two groups are similar both at 2 and at 5 years. In conclusion, TDR does not show significant superiority for the treatment of lumbar DDD compared with fusion. The benefits of motion preservation and the long-term complications are still unable to be concluded. More high-quality RCTs with long-term follow-up are needed.