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CLINICAL ARTICLE

Minimally invasive spinal surgery using nucleoplasty: a 1-year follow-up study

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Abstract
Background Nucleoplasty is a minimally invasive percutaneous intradiscal coblation therapy option in patients with chronic discogenic low back pain. The purpose of this prospective study was to assess the effectiveness of nucleoplasty in our patients up to 1 year after treatment.
Method All patients included in this study suffered from established back pain and/or radiating pain in the lower extremities. Age, gender, weight, body mass index (BMI) and smoking status were recorded and the clinical status of the patient documented using a visual analogue pain scale (VAS). Additionally, patients were asked to provide details regarding analgesic consumption, disability and ability to work. Nucleoplasty was carried out under fluoroscopic and CT-guidance. All treated patients were reviewed at 6 and 12 months.
Findings Between April 2005 and December 2006, 96 patients underwent nucleoplasty in our department. The 69 patients reported here were followed-up to 12 months while data for eight others is available only up to 6 months. Seven patients were lost to follow-up, while eleven were excluded due to a secondary disc sequestration, either at the treated segment or elsewhere. The mean age of the 27 females (39%) and 42 males in this study was 42 years (range 18–74). The mean duration of symptoms was 30.5 months (range 1–120). Forty-two percent of patients were smokers and the mean BMI was 26.3 (17.4–42.4). 73% of treated patients experienced an improvement of more than 50% in their symptoms in the early post-operative VAS score. This was reduced to 61% at 6 months post-operatively and 58% after 1 year. A statistically significant reduction in analgesic consumption, disability and occupational incapacitation resulted from treatment with nucleoplasty.
Conclusions Nucleoplasty is an effective therapy for chronic, discogenic back pain which results in significant reductions in levels of disability and incapacity for work as well as decreased analgesic consumption.

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Introduction

The importance of effective, decisive treatment for chronic low back pain is demonstrated by two facts. Firstly, the ubiquitous nature of low back pain worldwide: lifetime prevalence in industrialised nations is estimated to be between 54 and 80% (4, 5, 38). Secondly, chronic low back pain precipitates a vicious chain reaction of disability, occupational incapacity (12, 28), substance abuse (3, 13), psychiatric symptoms (22, 29) and related secondary co-morbidities such as obesity, heart disease and liver disease (8, 17). Additionally, low back pain has a high impact on health systems in terms of both therapy costs and lost productivity, which can also affect the economy and society as a whole (21).

The causes of low back pain are manifold and can be caused by a single pathology or a group of pathological processes acting together. The pain can be muscular, disco-ligamentous, neuronal or bony in origin, or may arise from arthritis of the intervertebral facet joints or the sacro-iliac joint (18). Disc disruption is estimated to be the main source of pain in 39% of patients (32).

The direct causation of disc pain can either be chemical or mechanical. Initially, pain can result from damage to vertebral body endplates which has been shown to precede disc degeneration and which forms a strip of granulation tissue from the nucleus to the annulus (2, 26). Later, during disc degeneration with or without disc herniation, additional factors play a role in the pathogenesis of pain. Mechanical pressure of disc fragments on the aligning longitudinal ligament, dorsal root ganglion or neural structures is a common cause of pain. New theories have proven that neovascularisation and nerve ingrowth into the degenerated disc can cause pain through chemo-inflammatory and neurotransmitter pathways (10, 16).

In recent decades, a number of minimally invasive percutaneous methods have been developed to treat back pain caused by either contained, disrupted or degenerate discs. These methods are designed to cause minimal damage to disc and nerve structures. The aim of all these methods was to reduce the pressure inside the damaged disc in order to decompress the herniated disc and in turn relieve pressure on the nervous tissue (34). Techniques commonly used have included chemonucleolysis, manual and automated percutaneous discectomy and percutaneous laser discectomy (8, 15, 30, 34, 35).

Nucleoplasty is a minimally invasive percutaneous intradiscal treatment option for chronic low back pain. It is based on coblation technology using bipolar radiofrequency energy. It consists of two phases; tissue ablation and coagulation. Using the 1 mm Perc-DLE tissue ablation and coagulation SpineWand (ArthroCare Corporation, Sunnyvale, CA, USA) inserted into the disc space through a 17-guage needle under fluoroscopic guidance (Fig. 1).

During ablation, isotonic saline solution generates a plasma field between the electrodes and the tissue. As a result of the voltage gradient, charged particles accelerate towards the tissue and break the molecular bonds of the disc nucleus into its constituent molecules and gases. These gases escape through the needle. For each 0.5 cm movement of the wand, a zone of thermal coagulation with a radius of 1 mm is created, leading to collagen shrinkage. Both effects aim to reduce the intradiscal pressure by removing approximately 1 cm^3 of tissue with minimal thermal damage to surrounding tissue.

The purpose of this prospective study is to assess the effectiveness of nucleoplasty in the treatment of our patients over a follow-up period of 1 year. All patients suffered from chronic back pain with or without associated radiating leg pain arising from a contained disc herniation, and no other apparent pain-causing pathology. Efficacy was assessed by comparing the pain, disability in the activities of daily living and occupational incapacity before and after the procedure. Pre-operative pain duration, smoking and body mass index (BMI) were assessed as indicators of outcome.

Methodology

Between April 2005 and December 2006, 96 patients were treated with nucleoplasty in the neurosurgical department of the Unfallkrankenhaus Berlin. Data collection was prospective. Patients with back pain and/or pain radiating to the lower extremities were included in the study. In all patients, conservative treatment was attempted for at least 6 weeks except for a small number of patients who, due to high analgesic consumption and high levels of disability, were treated sooner with nucleoplasty. Exclusion criteria included the presence of free sequestrated disc in the spinal canal, spinal canal stenosis, disc prolapse that occupied more than a third of the canal, previously operated segments, severe neurological deficits or co-existing neoplastic or infectious disease.

The age, sex, weight, BMI and smoking status of all patients was recorded and the patient's symptoms assessed on a visual analogue pain scale (VAS). The duration of symptoms (in months) was recorded. The

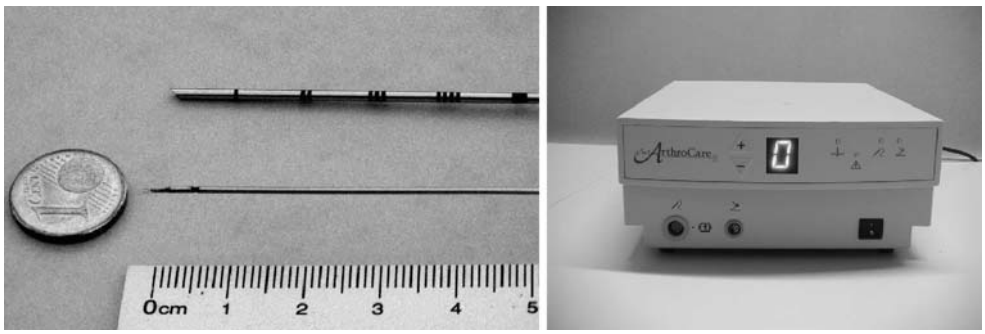

Fig. 1 *left* The 1-mm Perc-DLE tissue ablation and coagulation SpineWand—the middle needle (ArthroCare Corporation, Sunnyvale, CA, USA) in the central part of the figure is introduced into the disc space through a 17-guage needle, shown in the upper part of the figure. This is performed under fluoroscopic guidance. *right* The SpineWand is connected to the standard ArthroCare power generator

patient was asked to record their analgesic consumption, disability in the tasks of daily living and their degree of inability to work.

A pre-operative prophylactic dose of antibiotic (1.5 g Cefazoline) was given intravenously. The procedure was carried out in the prone position under sterile conditions. After infiltration of the skin and soft tissue with local anaesthetic, a 17-guage needle was introduced postero-laterally into the disc to be treated. Under fluoroscopic and CT guidance, the needle was placed into the posterior centre of the disc. A discography was carried out and patients found to have a disrupted posterior longitudinal ligament were excluded (Fig. 2).

Following insertion of the coblation bipolar device (Perc-DLE SpineWand connected to the standard Arthro-Care power generator), six channels were made to ensure adequate decompression of the disc space. After removal of the instruments, the incisions were closed and the patient ordered to rest in bed for 2 h. The VAS was assessed prior to discharge and the patient was told to resume normal activity levels. At 6 and 12-month follow-up, symptoms were again assessed by the VAS. Analgesic consumption, disability levels and occupational incapacity were also recorded. These data were converted for statistical analysis and are presented in Table 1.

Statistical analysis was performed using SPSS software. For the inferential statistics, Wilcoxon's signed rank test was used to find statistically significant differences between the pre- and post-operative VAS scores, the level of analgesic consumption and the levels of disability in daily living and work incapacity. The Spearman rank correlation test was used to analyse the effect of different factors on outcomes, including age, gender, duration of symptoms, smoking status and BMI. All analysis was conducted at the $p \leq 0.05$ level of significance. A positive post-therapeutic outcome for the patient was defined as a reduction in the pre-operative symptoms of at least 50%.

Results

Ninety-six patients were treated with lumbar nucleoplasty. Sixty-nine patients were included in the statistical evaluation having completed follow-up to 1 year. A further eight patients are included having been followed-up to 6 months. Seven patients were lost to follow-up while eight patients were excluded due to secondary disc sequestration in the treated segment. Two of these secondary sequestrations were caused by general trauma and four through lifting trauma. The other two were spontaneous sequestrations. All secondary sequestrations occurred approximately 4–6 months post-operatively. Additionally, three patients experienced a disc prolapse at a lumbar level other than that treated and were also excluded from the study. These excluded patients subsequently underwent microsurgical therapy. Finally, one patient was found on discography to have a perforation of the posterior longitudinal ligament and the procedure was aborted.

The mean age of the 69 patients included in the statistical evaluation was 42 years (range 18–74) with a gender distribution of 27 females (39%) and 42 males. The mean duration of symptoms was 30.5 months (range 1–120). 41% were smokers and the mean BMI was 26.3 (range 17.4–42.4). The VAS score for back pain had a mean of 6.59 pre-operatively, 2.50 immediately post-operatively, 3.10 after 6 months and 3.36 after 1 year. The mean VAS score for radicular pain was 5.68 pre-operatively, 1.40 immediately post-operatively, 2.54 after 6 months and 2.50 after 1 year (Fig. 3). Using Wilcoxon's signed rank test, it was found that a statistically significant difference existed between the pre-operative VAS score and that recorded in the 1-year follow-up ($p<0.005$), indicating an improvement in symptoms following nucleoplasty. This was true of both back pain and radicular pain (Fig. 3).

The percentage outcome score was calculated by dividing the difference between the pre- and post-operative

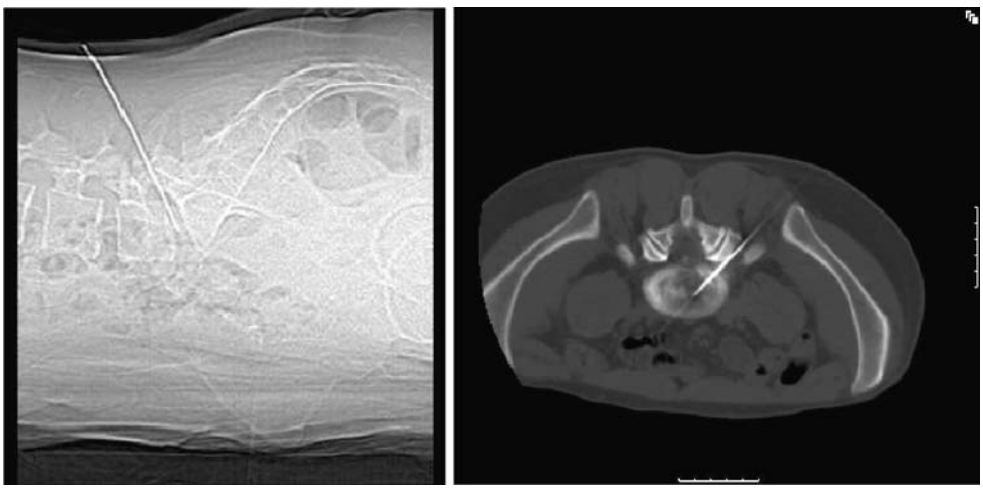

Fig. 2 *left* (CT scout) The 17-guage needle is introduced postero-laterally into the disc that is to be treated, in this case L5/S1. Under fluoroscopic and CT guidance, the needle is placed into the posterior centre of the discs. *right* (axial CT). The discography shows an in-homogeneous distribution of the contrast agent in the intervertebral disc space with an intact posterior longitudinal ligament, although contrast agent diffuses into the medio-lateral disc prolapse

Table 1 The analgesic consumption, disability and the inability to work were recorded according to the scoring scale shown above

Score	Analgesic consumption	Disability level	Occupational incapacity
1	None	None	None
2	Occasional weak analgesics	Mild impairment	Occasional
3	Occasional strong analgesics	Severe impairment	Frequent
4	Daily weak analgesics	Total incapacity	Continuous
5	Daily strong analgesics		

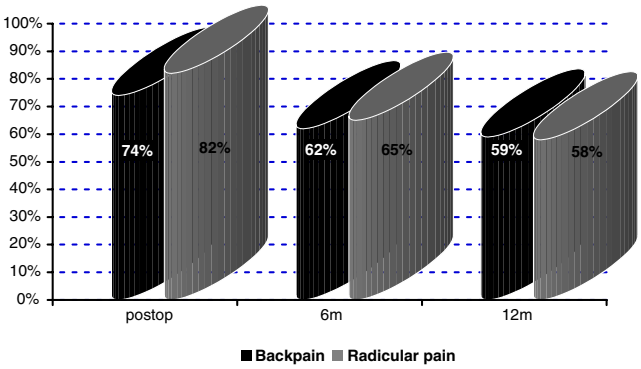

Fig. 4 Outcome after nucleoplasty: percentage of patients with an improvement of at least 50%, recorded immediately after the procedure and at 6 months and 12 months follow-up

VAS scores by the pre-operative VAS score and multiplying the result by 100. The outcome after the procedure showed an improvement in back pain symptoms of 50% or more in 73% of patients in the early post-operative phase, 61% after 6 months and 58% after 12 months (Fig. 4).

After 1 year of follow-up analgesic consumption was significantly reduced ($p<0.012$) following nucleoplasty. A significant improvement in levels of disability ($p<0.012$) and occupational incapacity ($p<0.005$) was also found (Fig. 5). The Spearman rank correlation test failed to show a statistically significant association between outcome score and duration of symptoms prior to therapy ($p=0.141$), smoking status ($p=0.56$) or BMI ($p=0.078$). A weak correlation was demonstrated between age and outcome score (correlation coefficient=0.321), indicating a trend towards better outcomes in younger patients.

Discussion

The effect of nucleoplasty will be discussed in relation to two aspects. The first is the effect of intradiscal decompression using the coblation technique. The advantage of removing only a small volume of disc tissue via nucleoplasty lies in the prevention of future, progressive disc degeneration (6). The amount of tissue removed correlates directly with a decrease in disc bulging and inversely with the loss of disc height. The effect of the decrease in intradiscal pressure by nucleoplasty has been discussed at length in the literature and remains controversial. In healthy disc specimens taken from human cadavers, Chen (7) demonstrated a significant reduction in disc pressure after coblation using only three channels. Since the tensional forces of the outer annulus have never been measured *in vivo*, the effect of pressure reduction can only be assumed. When a radial annular tear extends to the outer annulus, increasing nuclear pressure through injection of fluid into the disc will be reflected as a proportional increase in outer annulus pressure (20, 23). This is demonstrated when provocative discography (9) produces the adverse effect of intradiscal decompression in the disrupted discs.

The second element of nucleoplasty that requires consideration is the thermal effect on the disc tissue. Previous studies of the therapeutic effect of intradiscal electro-thermal therapy have shown that the temperature needed to modify the

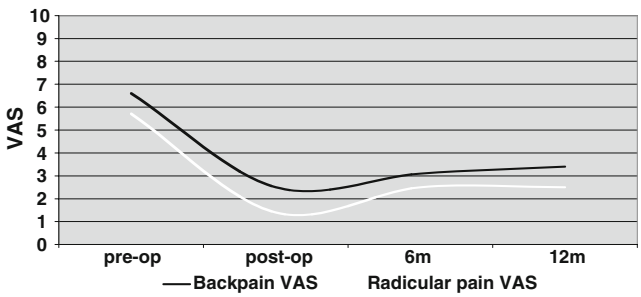

Fig. 3 Illustration of changes in subjective pain scores pre- and post-nucleoplasty and at 6 and 12 months after treatment using a VAS score for both back and radicular pain

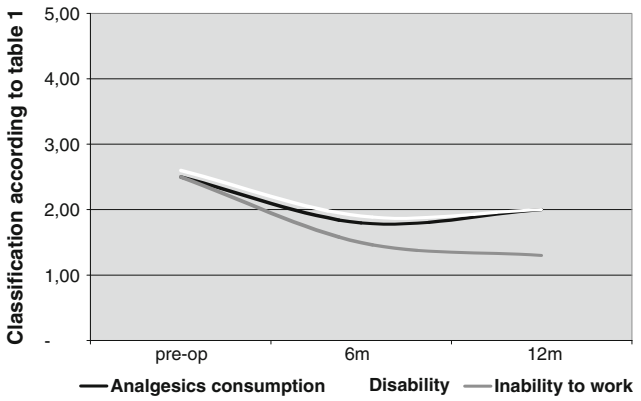

Fig. 5 Graph showing changes in analgesic consumption, disability level and level of occupational incapacity in patients treated with nucleoplasty pre- and post-nucleoplasty and at 6 and 12 months follow-up

annular collagen fibre architecture with consequential shrinkage was between 60 and 65°C. The threshold needed to thermocoagulate annular nerve endings and nocioceptors is between 40 and 45°C (14, 31). Nucleoplasty differs from intradiscal electrothermal therapy in the positioning of the device inside the nucleus and the minimal dispersal of the heat generated by the nucleoplasty device. This was demonstrated by Lee et al. (19) in ovine intervertebral discs. The nucleoplasty device nevertheless succeeds in generating temperatures of between 50 and 65°C (25).

From our discography results, 50 of the 69 patients (73%) studied were classified as stage 4 according to Adams' categorisation of discography findings in degenerative disc disease (1), a stage denoting a degenerative disc with fissures that reach the outer layer of the annulus. The results of this subgroup are particularly interesting. An improvement in outcome scores for back pain of more than 50% in 72% of these patients was demonstrated in the VAS results immediately post-operatively. These declined only slightly to 70% after 6 months and to 66% at the 1-year follow-up. In the patients with radicular pain, improvement in pain symptoms of more than 50% was reported by 80% of patients following their operation and by 66% at both 6- and 12-month follow ups. These results are similar to or even better than those from the whole patient sample. This suggests that the efficacy of nucleoplasty cannot but put down to the decrease in intradiscal pressure alone, as the highly degenerated discs in this group would have been significantly desiccated.

A possible explanation of the therapeutic effect can be found in the thermal effect of nucleoplasty. Attention is again drawn to the work of Peng et al. (26). In this study of the pathogenesis of back pain, fissures in the degenerated, painful discs were found to contain vascularised granulation tissue which formed from the nucleus to the outer part of the annulus as a reparative, reactive ingrowth. These zones of granulation contained mast cells. It has been suggested that mast cells synthesise, store and secrete nerve growth factor which may induce and promote nerve growth into the inner layer of painful discs (11). We hypothesise that the electrothermal coagulation during nucleoplasty will directly contact and ablate these painful intranuclear nerve endings.

Our results are comparable to other studies on the minimally invasive intradiscal application of coblation using nucleoplasty. Since we defined positive outcomes as a reduction of symptoms of at least 50% after 1 year, comparisons are best made with similarly structured studies. In one such study by Yakovlev et al. (39) featuring 22 patients, 68% showed a reduction of symptoms of at least 50% after 1 year. Singh et al. (34, 36, 37), conducted five studies into nucleoplasty; in 53% of the 67 patients studied, pain scores were reduced by at least 50% at 1 year. Reddy et al. (27) achieved a similar rate of 54% after 1 year in 67 patients. Other authors have defined the outcome by means of a patient satisfaction measure based on a reduction of pain on a VAS of at least two points. At 1 year after surgery, Sharps et al. (33) evaluated 49 patients and reported that 79% had reduced pain scores of at least two points. Masala et al. (24) noted a significant reduction in pain scores in their group of 72 patients 1 year following nucleoplasty.

This study is limited by the lack of patient randomisation and the absence of a control group undergoing conservative treatment only. Nevertheless, we consider percutaneous nucleoplasty as an effective, minimally invasive partial discectomy for the decompression of neural structures. While remaining aware of concerns regarding its long-term efficacy, we believe nucleoplasty should be regarded as an intermediate stage between conservative management and open surgical intervention.

Conclusion

Nucleoplasty is an effective, minimally invasive therapy option in the treatment of low back pain with or without radicular pain. As a result of a reduction in symptoms following nucleoplasty, the use of painkillers decreased and quality of life and ability to work increased, even in patients with severe intervertebral disc degeneration. It was impossible to refine the selection criteria to highlight potential differences in outcomes for variations in BMI, smoking status, pain duration and age.

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