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Surgical techniques of prosthetic disc-nucleus (PDN) replacement and early results of the PDN-SOLO device

Prostetik disk nükleusu (PDN) replasmanında kullanılan cerrahi teknikler ve PDN-SOLO cihazıyla elde edilen erken sonuçlar

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Objectives: Prosthetic disc-nucleus (PDN) replacement has the advantage that it can be performed with a minimally invasive technique, preserving the anterior longitudinal ligament, annulus fibrosus, and cartilaginous end plates. This study reviewed techniques and indications of surgical approaches and reported early clinical results of nucleus replacement with the PDN-SOLO device.

Patients and methods: From October 2002 to July 2004, a total of 167 patients were treated with the PDN-SOLO device, and clinical data of 70 patients whose follow-up period was more than three months were analyzed. Insertion of the device was performed with one of the following approaches: posterior, anterolateral transpsoatic, paraspinal transforaminal, and bilateral posterior approach.

Results: The mean preoperative Oswestry Disability Index score was 56%. It improved to 18.3% postoperatively. The mean visual analog scale scores for back pain were 7.5 and 2.5 before and after surgery, respectively. The results were successful in 60 patients (90%). Clinical failure was encountered in seven patients (10%), which included device extrusion (n=5), infection (n=1), and persistent back pain (n=1).

Conclusion: Early clinical results of the PDN-SOLO were found successful in patients with degenerative disc disease presenting with chronic back pain. The main complication of extrusion can be avoided through a successful implantation which warrants a high-level training on the detailed surgical technique and tactics of preparation of adequate space for the PDN-SOLO device.

Key words: Intervertebral disk displacement/surgery; prostheses and implants; prosthesis design; spinal fusion/instrumentation/methods.

Amaç: Prostetik disk nükleusu (PDN) replasmanı, minimal invaziv bir teknik olmasından dolayı avantajlıdır; anterior longitudinal ligamanı, anulus fibrozusu ve kartiloginöz end plate'lerin korunmasını sağlar. Bu çalışmada, PDN replasmanında kullanılan cerrahi teknik ve endikasyonlar gözden geçirildi ve PDN-SOLO cihazıyla yapılan nükleus replasmanının erken klinik sonuçları sunuldu.

Hastalar ve yöntemler: Ekim 2002 ile Temmuz 2004 tarihleri arasında 167 hastaya PDN-SOLO cihazıyla nükleus replasmanı uygulandı. Çalışmada, izlem süresi üç aydan fazla olan 70 hastanın klinik sonuçları değerlendirildi. Cihazın yerleştirilmesinde kullanılan yaklaşımlar dört grupta incelendi: Posterior, anterolateral transpsoatik, paraspinal transforaminal ve iki taraflı posterior yaklaşım.

Bulgular: Ameliyat öncesinde ortalama %56 olan Oswestry Sakatlık İndeksi ameliyattan sonra %18.3'e geriledi. Sırt ağrısı için görsel analog skala skorları ameliyat öncesi ve sonrasında sırasıyla 7.5 ve 2.5 bulundu. Sonuçlar 60 hastada (%90) başarılı bulunurken, 10 hastada (%10) cihazda gevşeme veya kayma (n=5), enfeksiyon (n=1) ve geçmeyen sırt ağrısı (n=1) nedeniyle başarısız sonuç alındı.

Sonuç: Kronik sırk ağrısı ile başvuran ve dejeneratif disk hastalığı olan olgularda PDN-SOLO cihazıyla replasmanın sonuçları başarılı bulundu. En önemli komplikasyon olan cihazda gevşeme veya kayma, ancak başarılı bir implantasyonla önlenebilir; bu da ayrıntılı cerrahi teknik ve PDN-SOLO cihazı için yeterli boşluk hazırlanması konusunda iyi bir eğitimi gerektirmektedir.

Anahtar sözcükler: İntervertebral disk replasmanı/cerrahi; protez ve implant; protez tasarımı; spinal füzyon/enstrümantasyon/yöntem.

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Chronic discogenic back pain caused by degenerative disc disease is a common ailment affecting the general population. Recently, spine arthroplasty is rapidly replacing arthrodesis in the surgical treatment of degenerative disc disease. Nucleus replacement, one of the spine arthroplasty procedures, unlike total disc replacement, preserves the anterior longitudinal ligament, the annulus, and the cartilaginous end plates and can be performed in a minimally invasive way.[1,2] Among several designs of nucleus replacement devices, prosthetic disc nucleus (PDN) has been used in humans for years and its clinical results have been reported.[3-5] Prosthetic disc nucleus itself has undergone changes with respect to design and surgical techniques, aiming to facilitate insertion and to prevent migration and extrusion of the device.[4] Even though the problem of device migration and extrusion has not been overcome completely, the incidence of the extrusion has decreased significantly since the last change in device design to PDN-SOLO.[6] Another progress in preventing the device extrusion is the refinement of the surgical technique. It has been appreciated that the preparation of the disc space is critical to prevent extrusion of the device.[5]

Techniques for PDN surgery can be divided into four categories depending on the approaches. Each approach has its own advantages and disadvantages and can be used in various indications. Therefore, one must choose an appropriate approach carefully, taking into consideration his/her experience with these approaches and the patient's pathology. The purpose of this study was to evaluate techniques and indications of each surgical approach and to report our early clinical results of the nucleus replacement with the PDN-SOLO device.

Surgical techniques

Posterior approach. This is similar to conventional discectomy (Fig. 1a). The preparation of the patient is the same as that in microdiscectomy. To insert the PDN after discectomy, laminotomy should be large enough for all instruments to pass easily. An annular incision is made transversely instead of creating a large opening. An extensive discectomy is performed and an effort is made to remove all the nucleus material so as to create enough room for the PDN device. With the use of intraoperative fluoroscopy, the preparation of the disc space is checked. Here, it is critical to make enough room especially in the lateral dimension of the disc, since the lateral dimension of dehydrated PDN is already 25 mm, once it is hydrated its size exceeds 25 mm. To secure the PDN in its position and to prevent its rotation, it is important that the space be more than 25 mm in the lateral dimension. The interpedicular distance of L_4 vertebra in Asian people is around 25 mm. Therefore, in an anteroposterior fluoroscopic view, the dye should fill the space from the medial border of the pedicle to that of the opposite pedicle (Fig. 2). Once the discectomy is adequate in the fluoroscope view, then serial annular dilators are used to dilate the annulotomy and device sizers are inserted into the space to choose a PDN of proper size. A specially designed flexible guide is inserted into the space and the PDN is introduced and rotated in a transverse direction. It is convenient to attach a suture on one pole of the PDN to pull it back in case it advances too far to the opposite side of the disc space (Fig. 3).

The posterior approach is especially useful in degenerative disc disease with concomitant disc herniation. It is advantageous, in that it can treat both back pain and sciatica. Though there are concerns about the development of postoperative peridural fibrosis and eventual new leg symptoms in patients who have pure degenerative disc disease without disc herniation and no leg pain before operation, our experience with the posterior approach is that the development of new leg symptoms after surgery is nil.

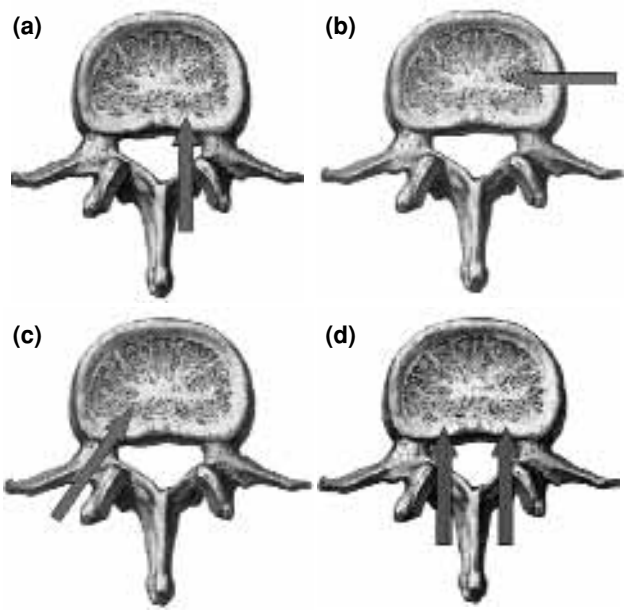

Fig. 1. (a) Posterior approach, **(b)** anterolateral transpsoatic approach (ALPA), **(c)** paraspinal transforaminal approach, **(d)** bilateral approach.

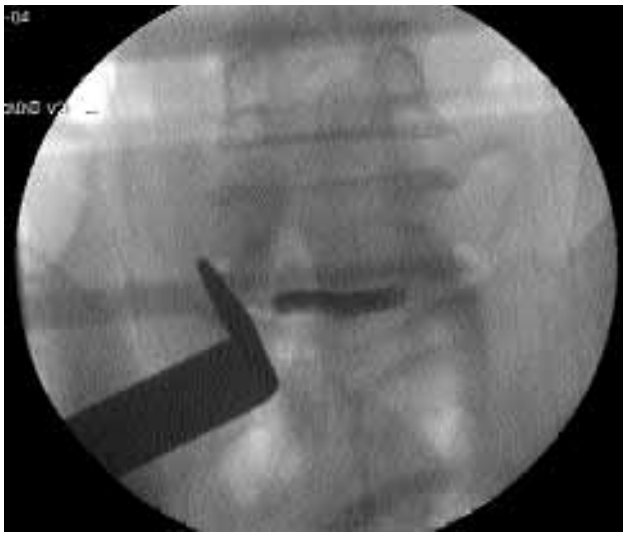

Fig. 2. Intraoperative discogram. The dye should fill the space from the medial pedicle line to that of the opposite side in the anteroposterior fluoroscopic view.

Anterolateral transpsoatic approach (ALPA). This approach was first described by Bertagnoli et al. (Fig. 1b).[3,7] The patient is placed in a right-lateral decubitus position. A skin incision is made on the left flank over the affected disc with the aid of fluoroscopic monitoring. The external and internal oblique muscles are retracted, the fascia of the transversalis muscle is punctured, and the retroperitoneal space is entered. Under fluoroscopic control, the correct disc space is identified and the psoas muscle is dissected bluntly in a longitudinal direction. The psoas muscle is then retracted to expose the disc and an annulotomy is made in a rotated H-shape. This shape facilitates the insertion of the PDN device and the repair of the annulus. After discectomy, the PDN device is inserted with the use of instruments specially designed for the ALPA technique. The annulotomy is closed with suture following proper positioning of the device.

The advantage of this technique is that it does not lead to postoperative peridural fibrosis that is thought be related with failed back surgery syndrome. This approach can be used for degenerative disc disease without herniation. A recent anatomical study showed that dissecting the muscle at L_{4-5} level was associated with injury to the lumbar plexus located in the posterior portion of the psoas muscle.[8] Leaving a split between the psoas muscle and the vertebral body was recommended without dissecting the muscle. Furthermore, since the instruments made for the ALPA technique are bulky, especially in anteroposterior dimension, the risk for lumbar plexus injury may be higher than anticipated. This technique is useful for L_{3-4} or above levels where the spinal canal is narrow and the passage of instruments and insertion of the PDN by the posterior approach are not easy. For these levels, the risk for lumbar plexus injury is less because the anatomic location of the lumbar plexus differs from that in the L_{4-5} level.

Paraspinal transforaminal approach. This approach is identical to that used for far-lateral disc herniation (Fig. 1c). The patient is placed in the prone position and a skin incision is made 5-6 cm lateral to the mid-

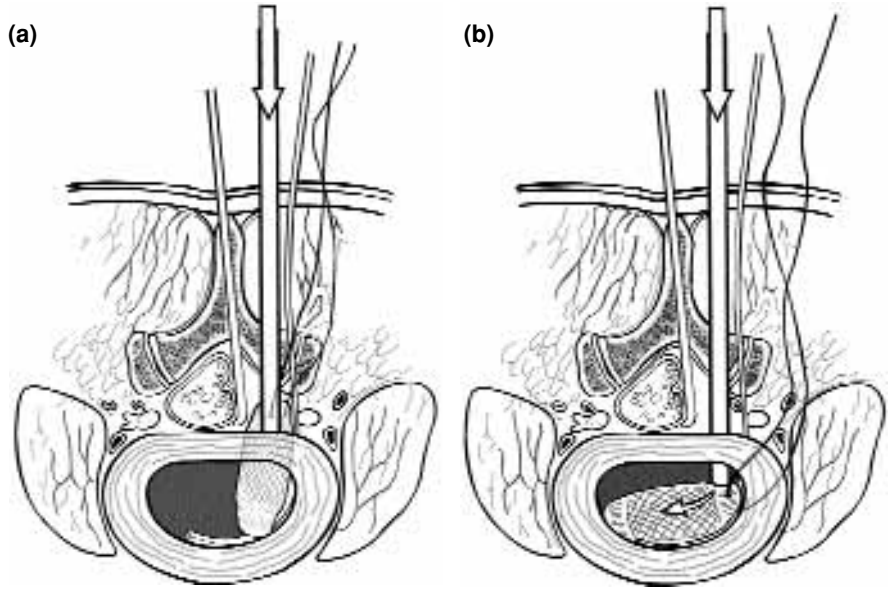

Fig. 3. (a, b) Insertion and positioning of PDN.

line. Fascia and muscle dissection is made in the usual way, moving down to the intertransverse membrane. The exiting nerve root is identified below the membrane. While carefully retracting the root, an annulotomy is made at the level of the neural foramen, and a discectomy is performed. The insertion of the PDN device is identical to that in the posterior approach. This approach can be used when there is concomitant far-lateral disc herniation without intracanal disc herniation. Its advantage is that it does not result in postoperative epidural fibrosis. However, it presents difficulty for the preparation of a rectangular disc space suitable for the placement and positioning of PDN.

Bilateral posterior approach. The procedure is the same as that used for the posterior approach except that laminotomy and the disc space preparation are performed bilaterally (Fig. 1d). One advantage of this approach is that it allows an effective removal of the contralateral nucleus, thereby creating adequate room for the PDN device. It is useful where the disc space is so narrow that insertion of the instruments and the PDN may be difficult. While a spacer is inserted into the disc to provide space, the PDN is inserted through an annulotomy on the opposite side. Another indication of this approach is recurrent disc herniation. Although there is debate regarding the treatment of recurrent disc herniation, it may be helpful if some stabilization procedure is added to the revision discectomy to prevent further collapse of the disc space and eventual chronic back pain associated with excessive removal of disc tissues. The dissection and retraction of the neural tissue to insert the PDN on the side of recurrence may be difficult and hazardous because of adhesions and fibrosis from the previous surgery. Through a bilateral approach, the PDN device is inserted through one side safely while the herniated disc is removed from the recurrent side.

PATIENTS AND METHODS

From October 2002 to July 2004, a total of 167 patients were treated with the PDN-SOLO device and clinical data of 70 patients whose follow-up period was more than three months were analyzed.

RESULTS

The mean preoperative Oswestry Disability Index score was 56%. It improved to 18.3% postoperatively. The mean visual analog scale scores for back pain were 7.5 and 2.5 before and after surgery, respectively. Clinical failure was encountered in seven patients (10%), including device extrusion (n=5), infection (n=1), and persistent back pain (n=1).

DISCUSSION

The PDN-SOLO device is effective in patients with degenerative disc disease presenting with chronic back pain with or without leg pain. The main problem associated with its use is extrusion of the device necessitating revision. To prevent extrusion, the surgeon should be well-trained on the detailed surgical technique and tactics of preparation of adequate space for the PDN-SOLO.

REFERENCES

1. Bao QB, Yuan HA. New technologies in spine: nucleus replacement. Spine 2002;27:1245-7.
2. Bao QB, Yuan HA. Prosthetic disc replacement: the future? Clin Orthop 2002;(394):139-45.
3. Bertagnoli R, Schonmayr R. Surgical and clinical results with the PDN prosthetic disc-nucleus device. Eur Spine J 2002;11 Suppl 2:S143-8.
4. Klara PM, Ray CD. Artificial nucleus replacement: clinical experience. Spine 2002;27:1374-7.
5. Shim CS, Lee SH, Park CW, Choi WC, Choi G, Choi WG, et al. Partial disc replacement with the PDN prosthetic disc nucleus device: early clinical results. J Spinal Disord Tech 2003;16:324-30.
6. Shim CS, Jung BJ, Choi G, Park SH, Hwang JH, Lee SH. PDN SOLO device vs. paired PDN devices: comparative study of early clinical outcomes. In: 44th Annual Meeting of the Korean Neurosurgical Society; October 13-17, 2004; Seoul, Korea. Abstract Book; p. 238.
7. Bertagnoli R, Vazquez RJ. The Anterolateral TransPsoatic Approach (ALPA): a new technique for implanting prosthetic disc-nucleus devices. J Spinal Disord Tech 2003; 16:398-404.
8. Moro T, Kikuchi S, Konno S, Yaginuma H. An anatomic study of the lumbar plexus with respect to retroperitoneal endoscopic surgery. Spine 2003;28:423-8.