Nonpenetrating deep sclerectomy with reticulated hyaluronic acid implant versus punch trabeculectomy: A prospective clinical trial

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PURPOSE. *To compare the intraocular pressure (IOP)–lowering effect and complication rate of nonpenetrating deep sclerectomy (NPDS) with reticulated hyaluronic acid (SK-GEL®) scleral implant versus traditional punch trabeculectomy (PT) in the management of primary open angle glaucoma (POAG).*

METHODS. *Prospective, randomized comparative study including 93 patients with uncontrolled POAG. Group 1 (43 eyes) underwent NPDS with SK-GEL® scleral implant; Group 2 (50 eyes) underwent PT. Mitomycin C (0.2 mg/mL) was applied intraoperatively in both techniques. Study follow-up evaluations were conducted at 36 and 48 months. Complete success indicated the achievement of the target IOP without antiglaucoma medications, while qualified success indicated the same goal with medications. These categories were assessed at two target IOP levels, <21 mmHg and <18 mmHg.*

RESULTS. *At 36 months for complete and qualified success with a <21 and <18 mmHg target IOP, no significant differences were noted between the two groups. At 48 months postprocedure when a <21 mmHg IOP target was considered, the rate of eyes that achieved complete success was 51.1% in the NPDS group versus 72% in the PT group ($p<0.05$). As for the <18 mmHg IOP target, the rate of eyes that achieved complete success was 32.5% in the NPDS group versus 44% in the PT group ($p<0.05$). Complications occurred significantly more frequently after PT than after NPDS.*

CONCLUSIONS. *The IOP-lowering effects of the two procedures were comparable at 36 months. At 48 months PT showed a significantly higher rate of complete success compared with NPDS. Complications were more frequent after PT than after NPDS. (Eur J Ophthalmol 2008; 18: 751-7)*

KEY WORDS. *Nonpenetrating deep sclerectomy, Punch trabeculectomy, SK-GEL® implant*

Accepted: February 14, 2008

INTRODUCTION

Trabeculectomy was introduced in 1968 and modifications of this technique are still considered the standard filtration surgery of glaucoma (1, 2). In the 1990s, an alternative surgical technique, nonpenetrating deep sclerectomy (NPDS), was developed in an effort to achieve a lower complication rate compared to the rate of intraoperative and postoperative complications associated with trabeculectomy (3-7). NPDS is a filtering surgery in which the internal wall of Schlemm canal is excised, allowing subconjunctival filtration of aqueous humor without surgical entry of the anterior chamber across the trabeculo-Descemet membrane (a process called "percolation") (3). As demonstrated in an animal model by Vaudaux et al (3), a potential advantage of NPDS is that it

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may reduce the risk of hypotony that occurs after trabeculectomy by creating progressive and reproducible filtration of aqueous humor from the anterior chamber to the subconjunctival space without penetrating the eye. Some clinical studies indicate that NPDS is less effective in reducing intraocular pressure (IOP) in the medium and long term than punch trabeculectomy (PT) (8). However, other authors have reported that, when intrascleral implants are used, NPDS yields better IOP-lowering results than PT (5). The aim of the current prospective randomized clinical trial is to compare the IOP-lowering effect and complication rate of NPDS with SK-GEL® implant versus traditional PT in the management of primary open angle glaucoma (POAG) refractory to maximum tolerated medical therapy.

METHODS

The study protocol was approved by the University of Foggia Institutional Review Board. All consecutive patients with POAG scheduled for glaucoma surgery at the Department of Ophthalmology of the University of Foggia between January 2000 and December 2001 were offered participation in the study if they met the following inclusion criteria: uncontrolled POAG on maximum tolerated medical therapy and no previous laser or surgical procedure (trabeculoplasty, iridotomy, phacoemulsification). Medically uncontrolled glaucoma was defined as an IOP >21 mmHg on maximum tolerated medical therapy or well-documented progression of visual field defects and/or glaucomatous optic nerve morphology. Exclusion criteria included angle closure glaucoma, secondary open angle glaucoma (pseudoexfoliative glaucoma, pigmentary glaucoma), having glaucoma surgery in conjunction with other ocular procedures (e.g., phacoemulsification), pregnancy, or a known allergy to collagen. Of the 98 patients who met the inclusion and exclusion criteria, 93 (94.8%) gave written informed consent to participate in the study. Preoperative data obtained for each patient included age, gender, ocular history, number of antiglaucoma drugs used at that time, best-corrected logMar visual acuity (BCVA), IOP measured by Goldmann applanation, slit-lamp examination, gonioscopy, fundus biomicroscopy, and visual field testing by Humphrey visual field analyzer using the 30-2 threshold SITA Standard program. Postoperatively, IOP, number of antiglaucoma medications, and complications were recorded on the first and the seventh day and at 1, 3, 6, 9, 12, 24, 36, and 48 months.

On the day of surgery, patients were assigned randomly to either NPDS with reticulated hyaluronic acid implant (SK-GEL®) or traditional punch trabeculectomy based on surgical chart number (patients with even numbers were assigned to NPDS and patients with odd numbers were assigned to PT). Surgical chart numbers were not assigned until the day of surgery.

Surgical techniques

Group 1 (NPDS). – After creating a superior fornix-based conjunctival/Tenon flap (6 × 6 mm), the sclera was exposed and hemostasis was achieved using bipolar cautery. A 5 × 5 mm, 200 µm thick scleral flap was dissected at the 12 o'-clock position and extended anteriorly 1 mm into clear cornea (Fig. 1, top left). A sponge soaked with mitomycin C (0.2 mg/mL) was applied beneath the superficial scleral flap for 2 minutes in all eyes. A second triangular deep scleral flap was then dissected, leaving only a very thin layer of deep sclera over the choroid. Anteriorly, the dissection was carried down to unroof and remove Schlemm canal and juxtacanalicular trabeculum. More anteriorly, the excision of corneal stroma was carried down to the level of Descemet membrane using a diamond knife (Fig. 1, top right). At this stage of the procedure, aqueous humor was observed to percolate through the trabeculo-Descemet membrane (Fig. 1, middle left). After excision of the deep triangular scleral flap (Fig. 1, middle right), a triangular 3.5 × 3.5 mm SK-GEL® implant (CORNEAL®, Paris, France) was placed in the center of the deep sclerectomy dissection site (Fig. 1, bottom left). The rectangular superficial scleral flap was then repositioned over the SK-GEL® implant and closed with 10-0 nylon sutures at each corner of the flap (Fig. 1, bottom right). The Tenon capsule and the conjunctiva were closed with 8–0 Vicryl suture.

Group 2 (PT). – Trabeculectomy was performed using the technique described by Cairns (1): after creating a superior fornix-based conjunctival/Tenon flap, the sclera was exposed, and hemostasis was achieved using bipolar cautery. A one-third thickness limbal-based 4 × 4 mm scleral flap was dissected and a sponge soaked with mitomycin C 0.2 mg/mL was applied under the scleral flap for 2 minutes in all eyes, after which an anterior chamber paracentesis was performed. The anterior chamber was irrigated with 1% acetylcholine solution (*Miochol E*, Novartis). A Crozafon-De Laage punch was introduced into

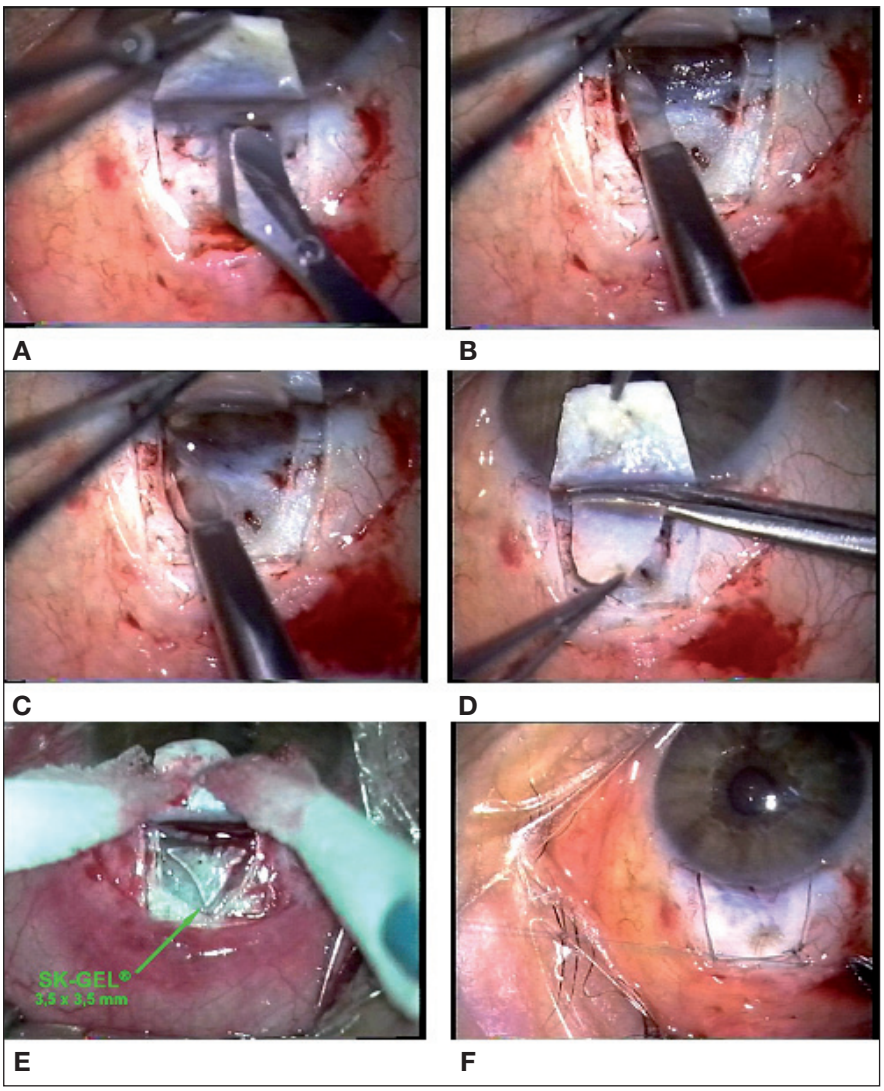

Fig. 1 - (A) *Creation of a superficial 5 x 5-mm scleral flap extending anteriorly 1 mm into clear cornea;* **(B)** *Deep dissection is finished exposing the trabeculo-Descemet membrane using a diamond knife;* **(C)** *aqueous humor percolates through the trabeculo-Descemet;* **(D)** *excision of the deep triangular scleral flap;* **(E)** *triangular 3.5x3.5 mm SK-GEL® implant (green arrow) was placed in the center of the deep sclerectomy dissection site;* **(F)** *the rectangular superficial scleral flap was repositioned over the SK-GEL® implant and closed with 10-0 nylon sutures at each corner.*

the anterior chamber and moved backwards to engage the deep plane of the posterior face of the peripheral cornea, thus creating a semicircular excision. The trabeculectomy was followed by creation of a peripheral iridectomy. The superficial flap was repositioned and secured with two 10-0 nylon sutures at each corner of the flap; the conjunctiva and Tenon capsule were closed with 8-0 Vicryl suture. Filtration was assessed by injecting balanced salt solution through the paracentesis site. Postoperatively, both groups were treated with a steroid-antibiotic eyedrop to the operated eye, tobramycin/dexamethasone (*Tobradex*, Alcon), three times a day for 4 weeks; tropicamide (*Visumidriatic* 1%, Visufarma) three times daily was added in the trabeculectomy group for 1 week. At any postoperative visit, if the filtering bleb showed signs of fibrosis or was encysted, subconjunctival injection of 5 mg 5-fluorouracil (0.1 mL 50-mg/mL 5-fluorouracil, *Fluoro-Uracil*, Roche) was administered in the lower quadrant opposite to the deep sclerectomy or trabeculectomy site. Subconjunctival injections were repeated up to seven times if necessary.

Complete success was defined as a target achieved without antiglaucoma medications, while qualified success was defined as a target IOP with medications.

These categories were assessed at two target IOP levels, namely ≤21 mmHg and ≤18 mmHg in the two groups, and a failure if IOP was >21 mmHg with maximum tolerated medical therapy, IOP <6 mmHg, or if an eye required further glaucoma drainage surgery, developed phthisis bulbi, or lost light perception.

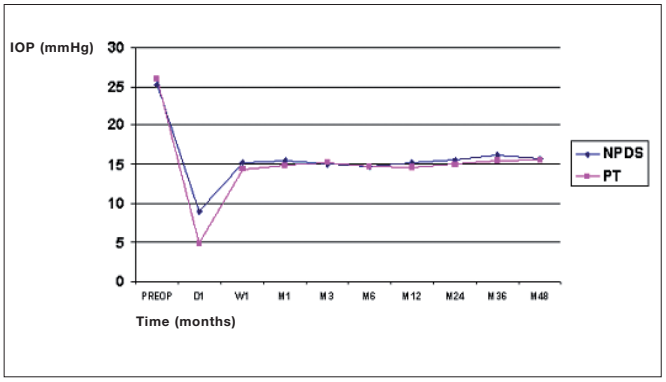

Fig. 2 - *Intraocular pressure over time in the NPDS and PT groups (mmHg).*

Statistical analyses

Results were analyzed using the *t*-test to compare the means. A p value of less than 0.05 was considered to be significant. The Wilcoxon signed rank test and the Poisson model were used for intergroup comparisons.

RESULTS

The study included 93 eyes of 93 patients: 43 eyes of 43 patients (23 men and 20 women with a mean age of 66.3±3.2 years) underwent NPDS (Group 1), and 50 eyes of 50 patients (24 men and 26 women with a mean age 68.2±2.1 years) underwent PT (Group 2) (Tab. I). The mean follow-up period was 47±12.3 months for the NPDS group and 46.4±14.1 months for the PT group (p=0.720), and the mean preoperative IOP was 25.3±3 mmHg and 26.0±2.8 mmHg, respectively (p=0.681). Demographic and baseline clinical characteristics are summarized in Table I. Figure 2 displays the IOP results over time. At day 1 the PT group had a lower mean IOP compared with the NPDS group (4.9±3.2 versus 8.9±4.1 mmHg, p=0.18). At 36 months, IOP was reduced by 39.9% in the NPDS group (15.2±3.3 mmHg versus 25.3±3 mmHg preoperatively), and by 42.7% in the PT group (14.9±2.8 mmHg versus 26.0±2.8 mmHg preoperatively) (p=0.720). At 48 months, IOP was reduced by 38.3% in the NPDS group (15.6±4.3 mmHg versus 25.3±3 mmHg preoperatively), and by 40.3% in the PT group (15.5±4.6 mmHg versus 26.0±2.8 mmHg preoperatively) (p=0.801).

The mean number of antiglaucoma medications employed to control IOP was reduced from 3.3±1.1 before surgery to 2.2±1.1 medications in the NPDS group and from 3.4±1.3 to 1.0±1.0 medications in the PT group (p<0.05) at 48 months.

At 36 months, when a ≤21 mmHg target IOP without medications (complete success) was considered, it was achieved in 74.4% (32/43) in the NPDS group and 74% (37/50) in the PT group (p=0.602). When a ≤21 mmHg target IOP with medications (qualified success) was considered, it was achieved in 88.3% (38/43) in the NPDS group and 86% (43/50) in the PT group (p=0.581) (Tab. II). When a ≤18 mmHg target IOP without medications (complete success) was considered, it was achieved in 41.8% (18/43) in the NPDS group and 44% (22/50) in the PT group (p>0.05). As for a ≤18 mmHg target IOP with medications (qualified success), 74.4% (32/43) and 78% (39/50) were found, respectively (p>0.05).

At 48 months, when a ≤21 mmHg target IOP without medications (complete success) was considered, it was achieved in 51.1% (22/43) in the NPDS group and 72% (36/50) in the PT group (p<0.05). When a ≤21 mmHg target IOP with medications (qualified success) was considered, the proportion of eyes that achieved qualified success in terms of IOP control was 81.3% (35/43) in the NPDS group and 86% (43/50) in the PT group (p=0.568) (Tab. II). When a ≤18 mmHg target IOP without medications (complete success) was considered, it was achieved in 32.5% (14/43) in the NPDS group and 44% (22/50) in the PT group (p<0.05). As for a ≤18 mmHg target IOP with medications (qualified success), 69.7% (30/43) and 74% (37/50) were found, respectively (p>0.05). At 48 months,

TABLE I - CHARACTERISTICS OF STUDY PATIENTS

	Total eyes	M	F	Age (yr)	Preoperative IOP (mmHg) and medication	5-FU (eyes)
Group I: NPDS	43	23	20	66.3±3.2	25.3±3–3.3±1.1	5
Group II: PT	50	24	26	68.2±2.1	26.0±2.8–3.4±1.3	2

IOP = Intraocular pressure; NPDS = Nonpenetrating deep sclerectomy; PT = Punch trabeculectomy

the mean number of antiglaucoma medications employed to control IOP was higher in the NPDS group (2.2±1.1) compared with the PT group (1.0±1.0) ($p<0.05$). In the NPDS group, the mean BCVA before surgery was 0.7±0.1. In the PT group the mean BCVA before surgery was 0.8±0.1 ($p>0.05$). At 48 months in the NPDS group, the mean BCVA was 0.6±0.1and in the PT group the mean BCVA was 0.4±0.1 ($p<0.05$). High-grade cataract occurred in 18% (9 of 50) of the PT patients versus 2.3% (2 of 43) of NPDS patients ($p<0.05$). In fact, we found a higher degree of cataract incidence in the PT group according to the classification of cataract of Chylack et al (9). One eye in the NPDS group experienced an iatrogenic microperforation of the thin trabeculo-Descemet membrane during deep sclerectomy dissection. No other intraoperative complications were noted in either group. Postoperative complications such as hyphema, hypotony (<6 mmHg), choroidal detachment, anterior chamber inflammation with fibrinous reaction (the score 0 to 4 was used to classify the severity of the clinical signs), early postoperative IOP elevation (>21 mmHg), and shallow or flat anterior chamber are listed in Table III. As a group, these complications occurred significantly more frequently after PT than after NPDS (Poisson model, $p=0.015$). The Wilcoxon signed rank test was performed to compare the rates of each complication type between the two groups. There was a significantly higher incidence of choroidal detachment ($p=0.007$) and flat anterior chamber ($p=0.023$) in the PT group but these complication rates were moderate and mainly transient.

The proportion of eyes that received subconjunctival injections of 5-fluorouracil postoperatively was 11.6% (5/43 eyes) and 4% (2/50 eyes) respectively in the NPDS group and in the PT group ($p<0.05$). In the NPDS group, the mean number of subconjunctival 5-fluorouracil injections was 2.3±1.0 and the mean time between surgery and 5-

TABLE II - COMPLETE AND QUALIFIED SUCCESS RATES AT 36 AND 48 MONTHS (percentage of eyes)

Intraocular pressure	36 mo	48 mo
Below 21 mmHg		
NPDS		
Complete success	74.4	51.1*
Qualified success	88.3	81.3
PT		
Complete success	74	72*
Qualified success	86	86
Below 18 mmHg		
NPDS		
Complete success	41.8	32.5*
Qualified success	74.4	69.7
PT		
Complete success	44	44*
Qualified success	78	74

*p<0.05 t test.
NPDS = Nonpenetrating deep sclerectomy; PT = Punch trabeculectomy

TABLE III - INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS OF NPDS AND PT

Complications	NPDS				PT			
	Intraoperative	Early	Medium term	Late	Intraoperative	Early	Medium term	Late
Microperforation of trabeculo-Descemet membrane	1 (2.3%)							
Wound leak	1 (2.3%)				2 (4%)			
Hyphema		1 (2.3%)				3 (6%)		
Flat anterior chamber						3 (6%)*		
Choroidal detachment						4 (8%)*		
Macular edema		1 (2.3%)				1 (2%)		
Hypotony (<6 mmHg)	2 (4.6%)					4 (8%)		
Cataract formation				2 (4.6%)				9 (18%)
Inflammation (score >2)		1 (2.3%)				2 (4%)		
Postoperative IOP elevation		1 (2.3%)				2 (4%)		

3 (6%)* 4 (8%)* *p<0.05 Wilcoxon signed rank test.
Early complication: first postoperative month. Medium term: second to sixth month. Late: after sixth month.
IOP = Intraocular pressure; NPDS = Nonpenetrating deep sclerectomy; PT = Punch trabeculectomy

TABLE IV - POSTOPERATIVE 5-FU INJECTIONS IN THE NPDS AND PT GROUPS

	NPDS	PT
Number of eyes	5 (11.6%)*	2 (4%)*
Mean number of injections for patients	2.3±1.0	3.5±1.6
Mean time between surgery and 5-FU injections (mo)	2.2±0.8	1.6±1.1

*p<0.05 t test.
NPDS = Nonpenetrating deep sclerectomy; PT = Punch trabeculectomy

fluorouracil injection was 2.2±0.8 months. In the PT group, the mean number of injections was 3.5±1.6 and the mean time between surgery and the 5-fluorouracil injection was 1.6±1.1 months (Tab. IV).

DISCUSSION

Several published studies suggested that NPDS and other nonpenetrating procedures are associated with a lower rate of successful IOP control than trabeculectomy, especially if the goal was a postoperative IOP below 18 mmHg (10, 11); however, the follow-up in these studies ranges from only 6 to 24 months. Nonpenetrating techniques (5, 12, 13) have not gained widespread acceptance among glaucoma surgeons due to intrinsic surgical difficulty, a steep learning curve, and inconsistent results. For these reasons, trabeculectomy, even if it is associated with a higher rate of postoperative complications that are usually transient, self-limited, and that resolved spontaneously, maintained its role of gold standard filtration procedure for surgical treatment of glaucoma (14). Published data indicate that the use of a punch technique can increase the speed, reproducibility, and safety of the trabeculectomy procedure (15, 16). However, many factors, such as population characteristics, quality of surgical dissection, use of intrascleral implant, and mitomycin C, can affect the surgical outcome of nonpenetrating procedures (5, 17, 18).

Fyodorov et al (19) reported the use of a collagen drainage implant in the scleral bed to promote filtration, with a mean follow-up of 18 months and a maximum follow-up of 36 months. Mermoud et al observed better IOP control and a lower rate of complications when an implant was used during NPDS (5, 14). Using ultrasound biomicroscopy (UBM) techniques, they concluded that IOP lowering was achieved by aqueous filtration through the thin remaining trabeculo-Descemet membrane to an area under the scleral flap, which was maintained open by the collagen implant (20, 21).

In terms of IOP control in our study, at 36 months, the complete success rate and the qualified success rate were similar for NPDS and PT groups both for IOP ≤21 mmHg and for IOP ≤18 mmHg. At 48 months, the complete success rate of the PT group (72%) was significantly higher than that of the NPDS group (51.1%) for IOP below 21 mmHg and 44% of PT and 32.5% of NPDS eyes for IOP below 18 mmHg ($p<0.05$), whereas the qualified success was similar for both groups (81.3% of NPDS and 86% of PT eyes for IOP below 21 mmHg and 69.7% of NPDS and 74% of PT eyes for IOP below 18 mmHg, $p>0.05$), but the mean number of antiglaucoma medications employed to control IOP was higher in the NPDS group (2.2±1.1) compared with the PT group (1.0±1.0) ($p<0.05$). These results indicate a gradual loss of IOP-lowering effect after NPDS over time. Visual acuity decreased more in the PT group compared with the NPDS group ($p<0.05$). Five eyes (15.1%) in the NPDS group developed an encysted or fibrotic bleb requiring postoperative subconjunctival 5-fluorouracil injections versus 2 eyes (4.8%) in the PT group. The incidence of early postoperative complications was lower after NPDS than PT. A similar lower rate of complications after NPDS compared with trabeculectomy was reported by Bylsma and El Sayyad et al (22, 23). The lower rate of early postoperative complications following NPDS suggested that PT was associated with more frequent excess filtration-related postoperative problems. Some of these problems, such as shallow anterior chamber and choroidal detachment, could be reduced as reported by Cillino et al (24) when combined procedures are considered, possibly due to the elimination of other conditions which predispose to a flat anterior chamber. There is controversy about considering NPDS as an alternative to standard trabeculectomy, primarily because the IOP control following NPDS has been reported to decrease over time (10, 11). However, punch trabeculectomy is a rapid and effective method of controlling IOP (25). At 36 months, NPDS and PT exhibit a similar trend in IOP lowering. At 48 months, PT shows better results over NPDS in IOP lowering. NPDS could be more suitable in younger patients, without visual field defects due to a lower risk of cataract incidence. PT could be more suitable in elderly subjects with documented pro-

gression of visual field defects to achieve a lower IOP target. Further studies are needed to evaluate the long-term functional and anatomic outcomes of PT and NPDS.

No author has a financial conflict of interest in the subject matter of the article.

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