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Clinical Application of the Provox® NiD™ Voice Prosthesis: A Longitudinal Study

Jan S. Lewin, PhD¹, Martha A. Portwood, MPH¹, Yijia Wang, MD, MPH^{1,2}, and Katherine A. Hutcheson, PhD¹

¹Department of Head and Neck Surgery, The University of Texas, MD Anderson Cancer Center, Houston, Texas 77030

²The Division of Epidemiology, Human Genetics and Environmental Sciences, The University of Texas, School of Public Health, Houston, TX

Abstract

Objective—To evaluate the indications, complications and device life of the Provox® NiD™ in a large cohort at a tertiary U. S. cancer center.

Study Design—Longitudinal retrospective cohort study.

Methods—We reviewed the records of patients who used the NiD™ prosthesis (2005–2011) for general indicators, device life, and complications.

Results—186 patients who used the NiD™ were included (median follow-up: 21.4 months). The NiD™ was placed at initial fit in 41 (22%) patients, whereas 145 (78%) tried an NiD™ after using another type of prosthesis. Most patients used the NiD™ similar to an indwelling device. Median NiD™ device life was significantly longer than that of other non-indwelling prostheses (45 vs. 29 days, $p=0.0061$), and did not significantly differ from that of standard indwellings (45 vs. 50 days, $p=0.4263$). Thirty-eight percent (71/189) of NiD™ users had a history of early leakage (<8 weeks) using a different prosthesis before trying the NiD™. Among patients with a pre-existing history of early leak, almost 90% of NiD™ prostheses out-performed device life of other products.

Conclusion—The NiD™ prosthesis offers satisfactory device life, on par with indwelling prostheses in our cohort of NiD™ users. Coupled with favorable published airflow characteristics and satisfactory TE voice, these data suggest that the NiD™ offers a durable, low-cost prosthetic alternative in contemporary practice. A unique indication for NiD™ may be improved device life in some patients with a history of early leakage.

Keywords

Provox® NiD™; voice prosthesis; total laryngectomy; tracheoesophageal puncture

INTRODUCTION

Tracheoesophageal puncture (TEP) remains the gold-standard for alaryngeal voice restoration after total laryngectomy.¹ The appropriate selection and placement of a tracheoesophageal (TE) voice prosthesis that is well-matched and acceptable to patients is key to successful voice restoration. The TE voice prosthesis is a one-way silicone valve that is placed into the TEP to allow phonatory air through the puncture and prevent aspiration. Despite the multitude of available prostheses, all depend on occlusion of the tracheostoma to direct pulmonary air through the prosthesis to vibrate the pharyngoesophagus for speech production. TE prostheses vary according to a variety of parameters including length, diameter, and method of insertion, and are mainly divided into 2 types, “non-indwelling” and “indwelling” prostheses. Non-indwelling prostheses can be placed by trained medical professionals or by non-clinicians including the TE speaker him- or herself. Alternatively, placement of indwelling prostheses has been approved only by medical professionals. The choice of a non-indwelling or indwelling prosthesis is based on general indicators that include patient characteristics and TE speech quality, the ability of the prosthesis to alleviate complications associated with leakage and aspiration, and device life. Patient preference often revolves around the ease of TE speech production and the cost of the prosthesis, both of which are influenced by the above categories. To date, experience and data support the popularity of the indwelling device over the non-indwelling device because of patient-perceived improvement in TE speech, reduced leakage, and increased device life.¹

The Provox® NiD™ voice prosthesis (Atos Medical AB, Hörby, Sweden) has gained popularity in the United States since it was cleared for marketing by the FDA in 2005.² Although marketed as a non-indwelling prosthesis, the NiD™ offers advantages that may make it an attractive often lower-cost alternative to the indwelling prostheses. Our experience in the last 8 years suggests that this device offers high patient satisfaction, better than expected durability in patients with early leakage, and favorable voice quality. Others have also reported encouraging results including lower airflow resistance during speech production, less prosthetic dislodgement, and better voice satisfaction over other non-indwelling prostheses.³ We, therefore, sought to describe our practice patterns and outcomes using the Provox® NiD™ in a large cohort of patients in a tertiary U. S. cancer center. The primary purpose of this study was to describe the general indicators, device life, and complications associated with use of the NiD™. We also discuss the NiD™ as a low-cost alternative to indwelling prostheses.

MATERIALS AND METHODS

Study Design

A longitudinal retrospective cohort was examined. All laryngectomized patients with a TEP who used a Provox® NiD™ at The University of Texas MD Anderson Cancer Center (MDACC) between March 1, 2005 and September 30, 2011 were eligible for inclusion. All consecutive laryngectomy patients seen in the study period (N = 522) were examined, and 186 who had an NiD™ placed were included. Customized NiD™ prostheses⁴ were excluded from analysis. Institutional review board approval and a waiver of informed consent were obtained.

TEP Management at MDACC

Both primary and secondary TEP are performed at MDACC. A red rubber catheter (12–14-French) is used to stent the TEP in the immediate postoperative setting. A voice prosthesis is placed 7–10 days postoperatively after primary TEP and 3–5 days after secondary TEP. Standard practice is to dilate the TE tract to 18-French and insert a 16- or 17-French prosthesis on the date of initial prosthetic fitting. A variety of indwelling and non-indwelling voice prostheses are used (InHealth Technologies, Carpinteria, CA; Atos Medical AB, Hörby, Sweden). Prostheses are selected at the discretion of the treating clinician based on product specifications and patient feedback regarding voice satisfaction and comfort. The NiD™ is frequently chosen as the initial product over other types of non-indwellings because our early experience suggested that many patients perceived easy voicing abilities using the NiD™.

Although the FDA cleared the NiD™ for use as a non-indwelling device, and the intended use of the device per the Instructions for Use reads: “The Provox® NID™ voice rehabilitation system is intended for use in prosthetic voice rehabilitation after total laryngectomy only by patients who have been trained in the use of the device and, as assessed by the clinician who prescribes the device, have demonstrated the ability to understand and consistently follow the Instructions for Use without clinician supervision” (Atos Medical AB, Hörby, Sweden), in our practice some patients elect to use the NiD™ similar to an indwelling device based on: 1) cleaning of the NiD™ in situ by the patient, and 2) replacement of the device exclusively by a trained clinician. That is, patients using the NiD™ similar to an indwelling device at our institution do not change their own prosthesis. However, all patients who use the NiD™ prosthesis are trained in the care and management of the device per the manufacturer’s Instructions for Use.

Variables

Data sources included the MDACC TEP Tracking Database and retrospective review of the electronic medical record. Three domains were reviewed including: general indicators, device life, and complications associated with use of the NiD™. Tumor staging, treatment, anatomy, and independence for TEP management were classified as general indicators. Device life was calculated in days from the insertion date to the removal date. Prostheses that dislodged or were removed outside of MDACC with no documented date of removal in the medical record were excluded from analysis of device life. For device life calculations, “standard indwelling” prostheses included the Provox®2, Blom-Singer® CLASSIC™ Indwelling, and Provox® Vega™. “Other non-indwelling” prostheses combined all non-indwelling devices except the NiD™ and included the Blom-Singer® Low Pressure, Blom-Singer® Duckbill, Bivona® Ultra Low, and Bivona® Duckbill. Aspiration of the NiD™ was confirmed radiographically or per endoscopy. Retail costs of indwelling prostheses generally range from \$189 to \$1,883 compared with non-indwelling costs that range from \$45 to \$98. Exact product costs vary according to manufacturer and institutional pricing, but in general indwelling devices remain more costly.

The first use of the NiD™ was classified as “initial fit” among patients whose first prosthesis placed into a new TEP was an NiD™, or “switch” among patients fit with an

NiD™ after trying other voice prostheses. Indications for switch included: difficulty voicing, gastric filling, and/or early prosthetic leakage through the valve (<8 weeks); or not specified when no indication for placement was specified in the medical record. Pre-existing early leakage was further stratified as occurring: <2 weeks, 2–4 weeks, or 5–8 weeks after placement. Leakage around the prosthesis was not queried as an indicator for switching to the NiD™. In our practice, the standard NiD™ is not used to manage leakage around a prosthesis because of the small diameter of the esophageal flange.

Statistical Methods

Descriptive statistics were calculated to summarize general indicators, device life, and complications. Kaplan-Meier survival analysis was used to examine prosthetic life. The log-rank test was performed to assess the differences between NiD™ subgroups, stratified by indications for removal, follow-up period, radiotherapy history, extent of surgery, and pre-existing early leakage. Analysis of device life of the NiD to other prostheses was compared within subjects of NiD users. Statistical significance was considered α -level .05. Statistical analyses were performed using the STATA data analysis software, version 10.0 (StataCorp LP, College Station, TX).

RESULTS

Patient Cohort

The study population included 186 patients who had an NiD™ placed at MDACC between 2005 and 2011, with median follow-up of 21.4 months (range: 0 to 73.4). Table 1 summarizes demographic, disease, and treatment characteristics. The median age of patients was 59 years (range: 33 to 86); 82% (152/186) were male. Most (111/186, 60%) had a history of glottic or subglottic cancer. Seventy three percent (135/186) underwent total laryngectomy, and the remainder required extended surgery including a partial (33/186, 18%) or total pharyngectomy (18/186, 10%). The pharynx was closed primarily in most patients (128/186, 69%). Eighty seven percent (162/186) had a history of radiation therapy, 54% (100/186) prior to laryngectomy and 33% (62/186) postoperatively. Over half of patients had primary TEP (102/186); 13 (7%) patients who underwent primary TEP required repeat puncture during the study period. Fifty seven percent (106/186) of patients had NiD™ prostheses replaced by speech pathologists exclusively, 16% (30/186) self-replaced exclusively, and 27% (50/186) alternated between replacement by a speech pathologist and self-replacement.

Device Characteristics

A total of 2,614 voice prostheses were placed in the 186 patients during the study period. Of the prostheses placed, 28% (n=727) were NiD™ prostheses, among which 675 non-customized NiD™ were examined in this analysis. The most common sizes were: 20-French diameter, and 10-mm (115/675, 17%) and 8-mm (114/675, 17%) lengths. Table 2 presents device specifications of the 675 NiD™.

Indications for First Use of the NiD™

Figure 1 shows the indications for first use of an NiD™ among the 186 subjects. The NiD™ was selected at initial fit because of the indication for a non-indwelling device in 41 (22%) patients, whereas 145 (78%) switched to an NiD™ after wearing another type of prosthesis. Prosthetic problems cited at the time of switching to an NiD™ in 116 (62%) patients included early leakage (71/186, 38%), difficulty voicing (50/186, 27%), and gastric filling (37/186, 20%). Thirty six (19%) patients had more than one problem cited when switching to an NiD™. Most patients with a history of early leakage when switching to the NiD™ experienced leakage within 2 weeks of using other devices, and most (44/71, 62%) were using an indwelling prosthesis immediately preceding use of the NiD™.

Device Life of NiD™

Among the 675 NiD™ prostheses, 465 had known device life that contributed to a total follow-up time of 22,204 days (Figure 2). The median device life of all NiD™ prostheses was 30 days (IQR: 11 to 63 days). Device life of the NiD™ was further analyzed per stratifications illustrated in Figure 3. Stratified by indication for removal, median device life of NiD™ prostheses removed for prosthetic leak was 45 days compared with 15 days when removed for other indications (Figure 4a, $p < 0.0001$). Median device life in post-acute follow-up (>6 weeks after the TEP) was 41 days (Figure 4b, $p < 0.0001$). Seventy-one patients with history of early leak prior to switching to the NiD™ had a median device life of 53 days. Almost 90% of NiD™ prostheses (110/123, 89.4%) used in patients with a pre-existing leak out-last the upper limits of previous prostheses durational thresholds (<2 weeks, 2–4 weeks, or 5–8 weeks). Extent of surgery ($p=0.386$) did not significantly affect device life of the NiD™. Device life was also not significantly affected by radiation history; however, the 12 NiD™ prostheses placed in patients without a history of RT did last longer (median 78 days) than the 216 placed in patients with a history of RT (median 45 days, $p=0.190$).

NiD™ device life was then compared to other prostheses used in our cohort of NiD™ users. Median NiD™ device life was significantly longer than that of other non-indwelling prostheses (45 days vs. 29 days, $p=0.0061$) and did not significantly differ from that of standard indwellings (45 days vs. 50 days, $p=0.4263$). Specifically, when stratified by prosthesis type, the median device life to prosthetic leak was: 45 days for NiD™ prostheses ($n=228$ prostheses), 50 days for standard ($n=414$), and 29 days for other non-indwellings ($n=69$) (Figure 5).

NiD™ Outcomes

Eighty (12%) out of 675 NiD™ prostheses dislodged. One patient aspirated the NiD™ into the respiratory tract while attempting to change the device, but the prosthesis was retrieved endoscopically in the clinic. A safety feature of the NiD™ to prevent aspiration per the manufacturer's Instructions for Use is the attached medallion. In the patient who aspirated the NiD™, the medallion had been detached. Overall, 31% of patients continued to use the NiD™ prosthesis at last follow-up.

DISCUSSION

This study sought to describe our experience using the NiD™ prosthesis over the course of 6 years. In our clinical practice, we found that the NiD™ offers a reliable option for patients with diverse indications. Relative to other prostheses, the NiD™ offers comparable or extended durability, affordability, independent management, and favorable voicing. Outside of the patient population who demonstrate TEP enlargement or leakage around the prosthesis, we have found no particular subgroup of patients for whom use of the standard NiD™ cannot be attempted. Our sample included patients requiring flap reconstruction (28%), radiation (87%), and TEP formation as primary or secondary procedures (Table 1). Hence, we present our clinical experience in a sample of diverse and complex TE speakers representative of those who are managed in a large tertiary cancer institution.

In this study, patient satisfaction and quantitative voice outcomes were not collected. One of the motivating reasons for examining our outcomes using the NiD™ was because of the subjective enthusiasm reported by our patients for this device because of their sense of easy or effortless voice production. We suspect that the larger inner lumen diameter compared with other non-indwelling devices (17-Fr: 2.6-mm ID, and 20-Fr: 4-mm ID) provides less resistance to airflow resulting in less effortful voicing (Figure 6 illustrates the dimensions of the NiD™ prostheses). Our clinical observations are further supported by published data demonstrating better voice satisfaction and lower in vitro airflow resistance of the NiD™ compared with other popular nonindwelling prostheses.³

An important result of our analysis was that the device life of the NiD™ was better than that of other non-indwelling devices and comparable to that of standard indwelling devices worn in our sample of NiD™ users. The median device life of the NiD™ was 45 days (IQR: 27 to 81 days) to failure for prosthetic leakage. This was comparable to the device life of indwelling prostheses in our sample of NiD™ users and longer than the median device life of 29 days in other non-indwelling prostheses. NiD™ device life in our sample was also higher than the reported mean of 26 days for low-pressure and duckbill non-indwelling devices published in other series.⁵ We surmise that the design of the NiD™ that combines a larger inner lumen diameter with a dome-shaped valve offers the advantage of comparable and, in some cases, extended durability without compromising vocal effort. Although the life of the NiD™ was not as long as published median device life for indwelling prostheses (ranging from 89 to 111 days), evidence that the NiD™ lasts longer than other non-indwelling devices used by TE speakers in our NiD™ sample suggests that it offers an excellent alternative to the indwelling device for some patients. We acknowledge that other prostheses offer acceptable and sometimes better longevity among patients who were not included in this study. Bias is inherent in comparisons of devices in observational, retrospective studies such as this, and 62% of patients had experienced problems with other prostheses before trying the NiD™. So, the results of this study should be interpreted in the context of a within-subject comparison comprised largely of patients who experienced suboptimal longevity or performance with other styles. Our observations regarding device life require confirmation in randomized comparisons.

Our early experience using the NiD™ suggested that the NiD™ might be a “problem-solver” for early leakage. Thus, we further examined device life in the subgroup of patients with history of early leakage before switching to the NiD™. In our cohort, 38% of patients presented with a history of early leakage prior to switching to the NiD™ and 89% in this subgroup experienced improved device life with the NiD™. Although not an intended indication for use by the manufacturer, our analysis suggests that the NiD™ may offer an affordable option to extend device life in some TE speakers with intractable early leakage. NiD™ offers several advantages over specialty prostheses, such as those with increased-resistance valves and antifungal properties, typically used to combat early leakage. Patients’ report suggests that voicing is easier with the NiD™ compared with use of “increased-resistance” valves available in indwelling and non-indwelling types that are marketed to prevent early leakage. The NiD™ also provides a less costly alternative to specialty devices, and offers independent management for patients to change the device outside of the clinical setting. To our knowledge, no prior publications have assessed device life of non-indwelling prostheses in subgroups of early leakers. Thus, further prospective studies are required to confirm our results that suggest this unique indication for the NiD™ as a non-indwelling alternative to extend device life in patients with early leakage.

Finally, our experience also suggests consideration of the NiD™ for use in other clinical scenarios. Clinicians may opt for the NiD™ as a low-cost alternative to the indwelling device at the time of the initial fit when prosthetic durability and patient preferences have not been established. That is, use of the NiD™ as the initial prosthesis may provide equal durability and outcomes in an uncomplicated patient with no clear benefit to attempting a costlier indwelling device. If device life and voice are satisfactory, patients may continue to use the NiD™ as their long-term prosthetic choice thereby avoiding the unnecessary purchase of more expensive prostheses. In fact, we found that almost one-third of patients in this cohort continued to use the NiD™ as their long-term prosthesis of choice. In addition, the NiD™ offers the ability to independently change the voice prosthesis, an advantage that avoids the burden of travel, lost work hours, and expenses associated with multiple clinic visits. The current healthcare reimbursement system in the United States poses an additional challenge to TE speakers. The ability to directly purchase the NiD™ prosthesis may be of significant value to patients whose access to indwelling devices is limited by third party payers. In most instances, patients can directly order the NiD™ and obtain third party reimbursement.

CONCLUSION

The NiD™ voice prosthesis offers satisfactory device life, on par with that of standard indwelling prostheses in our cohort of TE speakers who tried the NiD™. Coupled with published outcomes demonstrating favorable airflow characteristics and superior TE voice, our data suggest that the NiD™ offers a durable, affordable prosthetic alternative to more expensive indwelling devices in some TE speakers. When reimbursement limits patient access to indwelling devices, the NiD™ voice prosthesis may provide a comparable experience with the advantage of independent management. A unique indication for NiD™ may be to improve longevity of device life in patients with a history of early leakage.

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Figure 1.

Indications for first NiD™ use.

*immediate post-fit leak, patient's request, for independent placement, superior tract migration

N = 186

Figure 2.
NiD™ device life.
Excludes prostheses customized or dislodged, and those replaced outside of MDACC
N = 465

Figure 3.
Flow chart.

*not evaluable, replaced at home or outside hospital

**indwelling use, clinician replaced at MDACC

n = number of NiD™ prostheses contributing to device life calculations within strata

Figure 4.

a. NiD™ device life stratified by indication for removal.

Excludes prostheses customized or dislodged, and those replaced outside of MDACC

N = 465

b. NiD™ device life stratified by acute and post-acute follow-up periods.

Excludes prostheses customized or dislodged, and those replaced outside of MDACC

N = 465

Figure 5. NiD™ device life compared with standard indwelling and other non-indwelling (not NiD™) prostheses. Excludes prostheses customized or dislodged, and those replaced outside of MDACC
N = 1,382

Figure 6.
Dimensions of the NiD™ prostheses.

Table 1

Sample characteristics (n= 186 NiD™ patients)

		No.	%
Sex	Male	152	81.7
	Female	34	18.3
Tumor site	Glottic/subglottic	111	59.7
	Supraglottic	38	20.4
	Hypopharyngeal	16	8.6
	Oropharynx	7	3.8
	Thyroid	8	4.3
	Other *	6	3.2
T Stage	0–2	13	7.0
	3–4	70	37.6
	Recurrent	91	48.9
	Unknown or N/A	12	6.5
N Stage	N0	35	18.8
	N+	46	24.7
	Recurrent	91	48.9
	Unknown or N/A	14	7.5
Surgery**	TL	135	72.6
	TL + PP	33	17.7
	TLP	18	9.7
Reconstruction	None	128	68.8
	Patch flap (pharynx)	35	18.8
	Circumferential flap (pharynx)	18	9.7
	Tongue	5	2.7
Radiation	None	24	12.9
	Pre-operative RT	100	53.8
	Post-operative RT	62	33.3
Timing of TEP	Primary	89	47.8
	Secondary	84	45.2
	Both	13	7.0
1st use of NiD®	Initial prosthesis fit	41	22.0
	Switched from other device	145	78.0

* Cervical esophagus, Unknown Primary, Trachea, Oral Cavity

** TL: total laryngectomy / total laryngectomy + partial glossectomy / total laryngectomy + total glossectomy;
 TL + PP: total laryngectomy + partial pharyngectomy / total laryngectomy + partial pharyngectomy + partial glossectomy;
 TLP: total laryngopharyngectomy / total laryngopharyngectomy + partial glossectomy / total laryngopharyngectomy + total glossectomy

Table 2

Device specifications (N= 675 NiD™ placed)

	No.	%
Prosthesis Diameter 17 Fr		
Length		
6 mm	33	4.9
8 mm	70	10.4
10 mm	72	10.7
12 mm	34	5.0
14 mm	41	6.1
18 mm	31	4.6
All 17 Fr	281	41.6
Prosthesis Diameter 20 Fr		
Length		
6 mm	45	6.7
8 mm	114	16.9
10 mm	115	17.0
12 mm	91	13.5
14 mm	17	2.5
18 mm	12	1.8
All 20 Fr	394	58.4