Indications for the Gasless Transaxillary Robotic Approach to Thyroid Surgery: Experience of Forty-Seven Procedures at the American Hospital of Paris

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Key Words

Thyroid disease · Transaxillary robotic thyroid surgery · Cosmesis

Abstract

Background: Thyroid surgery is in a state of evolution from traditional open approaches to novel robotic techniques. The gasless transaxillary approach to thyroid surgery is effective in the management of thyroid cancer, and complications after robotic thyroidectomy are no higher than experienced after open or endoscopic techniques. The transaxillary robotic approach also avoids an anterior neck scar. This paper presents what the authors believe to be the largest cohort of patients reported in Europe undergoing gasless transaxillary robotic thyroid surgery, with the aim of defining the indications for this procedure. **Methods:** Forty-six patients underwent robotic thyroid surgery via the transaxillary approach and were enrolled in this study between March 2010 and September 2012. All patients were operated on by one surgeon at one clinical center. Reviewed data included patient characteristics, pathological characteristics, extent of surgery and postoperative complications. The mean follow-up time was 7.29 months. **Results:** Forty-six patients underwent 47 procedures, the average age of the patients was 43 years

and the male to female ratio was 1:22. Undertaken were 30 lobectomies, 3 subtotal thyroidectomies, 13 total thyroidectomies and 1 totalization. One case was converted to an open procedure. The ratio of malignant to benign disease was 1:6.67 (6:40 cases) and analysis of the surgical specimens showed 6 follicular lesions, 24 follicular adenomas, 3 colloid lesions, 1 case of thyroiditis/lymphatic lesion, 3 adenomatoid lesions, 3 oncocytic adenomas, 3 papillary cancers and 3 microcapillary cancers. The overall average size of an individual specimen removed was $45.40 \pm 28.95 \text{ cm}^3$ (range 5–160, $n = 47$) and the average largest diameter of the lesion removed was $3.72 \pm 0.95 \text{ cm}$ (range 1.4–6.0, $n = 47$). Postoperatively, there were 5 recurrent laryngeal nerve injuries (4 transient), 2 transient brachial plexopathies, 1 case of postoperative dysphagia and 1 of collection of blood at the site of surgery. There were no cases of disease recurrence at follow-up. **Conclusions:** The gasless robotic transaxillary approach to thyroid surgery has been predicted to become a standard technique. It has been shown to be efficacious in the management of thyroid cancer with lateral neck metastases; however, more data relating to oncological safety in long-term follow-up is required. This intervention is also appropriate for benign thyroid disease including Graves' disease. To achieve consistently successful results, careful patient selection is fundamental in terms of patient characteristics and

the anatomical aspects of the lesion. This is especially important with a geographical expansion to include North America and Europe. The excellent cosmetic results of this procedure make it ideal for patients who have esthetic concerns regarding particular difficulties with healing; however, in common with all new surgical procedures, further evidence must be sought to confirm its indications over time.

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Introduction

Thyroid surgery is continually evolving and robotic and minimally invasive techniques have irreversibly altered the surgical approaches used. The traditional open technique provides direct visualization and safe dissection with low patient morbidity and mortality [1]; however, the midline incision can lead to scarring and neck contractures which may be cosmetically unacceptable [2]. Endoscopic alternatives, including minimal cervical incisions and axillary approaches [3–6], have been attempted. However, the difficulties are numerous and include limited 2-dimensional views and difficult instrument manipulation due to a narrow working space [7].

It is for these reasons that robotic techniques using the da Vinci Surgical System (Intuitive Surgical Inc., Sunnyvale, Calif., USA) have recently emerged. The da Vinci System provides a 3-dimensional magnified picture, downscaling of motion to allow fine movement, dampening of physiological tremor and improved range of motion via multiarticulated instruments [8, 9].

The use of the da Vinci System in the gasless transaxillary approach to thyroid surgery has been proven to be effective in the management of thyroid cancer [10–15]. It is superior to endoscopic techniques in terms of completeness of resection [2], and complications after robotic thyroidectomy are no higher than experienced after open [10] or endoscopic techniques [15]; this is attributed mainly to the excellent surgical field view. The chief benefit of a transaxillary robotic approach is the avoidance of scarring in the anterior neck, and patients express subjective satisfaction with scar cosmetics [16]. Further benefits include a reduced risk of postoperative airway compression by hematoma as the working space is large [11], and better swallowing and functional voice outcomes in comparison to open thyroidectomy [17], findings attributed to less invasive techniques with limited strap-muscle dissection and reduced adhesion between the strap muscles. The gasless transaxillary approach was originally described in Korea [12–14], and experience has shown that

modifications are necessary when operating in other populations [11]. Despite this, it is still a successful and viable technique.

As with all novel surgical methods, there has been resistance to the introduction of the robotic approach [18]; however, a recent review proposed that robotic thyroidectomy will become the standard technique for thyroid surgery [19]. This paper presents what the authors believe to be the largest cohort of patients reported in Europe undergoing gasless transaxillary robotic thyroid surgery, and has the aim of responding to the yet-unanswered questions of definitive indications for this procedure.

Patients and Methods

Patients

Between March 2010 and September 2012, 46 patients enrolled in this study and underwent gasless transaxillary robotic thyroid surgery, operated on by a single surgeon (P.A.) at a single institution (the American Hospital, Paris). One patient underwent right-sided lobectomy followed by left-sided totalization 14 days later, providing data for two separate procedures. A proforma from the American Robotic Thyroid Registry was completed during and after each procedure (suppl. appendix 1; for all online suppl. material, see www.karger.com/doi/10.1159/000350854). Preoperative diagnosis was made by ultrasound-guided fine-needle aspiration (FNA). The data reviewed included patient features, pathological characteristics (specimen size, tumor size, multiplicity, final pathological findings and the presence of parathyroid glands in the specimen), extent of surgery and postoperative complications. Three patients were given postoperative radioactive iodine, with the average dose being 3,807 MBq. The mean follow-up period was 7.29 ± 7.03 months (range 1–24).

Surgical Technique

Positioning

The patient is placed under general anesthesia and endotracheal intubation is performed using a tube incorporating electrodes to aid detection of injury to the recurrent laryngeal nerve (RLN) by stimulated electromyography of the vocal cords (Xomen NIM II EMG Endotracheal Tube II; Medtronic Inc., Jacksonville, Fla., USA).

The patient is positioned supine with a slightly extended neck [20] and the contralateral arm alongside the body [21]. The ipsilateral arm to the axillary incision in the first 6 patients was placed in an extended position as described by Chang et al. [22]; however, this was replaced by a modified position as described by Kuppersmith and Holsinger [11] for all other patients after instances of brachial plexopathy. Therefore, the ipsilateral arm is placed in position with an extended shoulder, right-angle-flexed elbow and forearm in front of the head in a padded and safe position on an arm board overlying the forehead [11]. Brachial plexus monitoring is undertaken using the NIM-Eclipse (Medtronic Inc.) to produce continuous intraoperative neuromonitoring of transcranial eclectic motor-evoked potentials. To perform this,

needle electrodes are placed in the biceps, triceps, extensor carpi radialis and flexor carpi ulnaris, and electrical stimulation is induced. Two subdermal needle electrodes over motor cortex regions C1 and C2 allowed stimulus delivery and the extensor carpi radialis in the contralateral arm was monitored to check the effective response and disappearance of muscle relaxation. Stimulation was performed in a neutral arm position, modified arm position before incision, during dissection of the working space, after retractor placement, during robotic working time, after removal of robotic instruments, after skin closure and after infiltration by 10–15 ml of 0.75% ropivacaine and placement of the ipsilateral arm alongside the body.

Incision

Skin markings are made. The medial border is the vertical line from the sternal notch to the midline of the thyroid [23], the inferior border of the dissection is a transverse line from the sternal notch to the ipsilateral axilla and the superior border is an oblique line from the thyrohyoid membrane drawn (at 60° with respect to the midline) to the ipsilateral axilla [23]. The vertical axillary incision is marked by the intersection of the superior and inferior borders of the dissection with the anterior axillary fold. The markings are made prior to arm positioning to check for scar concealment with the arm in a neutral position. After the patient is prepared and surgical drapes positioned, a 5- to 6-cm vertical incision is made using a scalpel through the skin and using electrocautery to the fascia overlying the pectoralis major muscle [11].

Creation of the Working Space

The dissection occurs along the anterior surface of the pectoralis major muscle, inferior to the overlying superficial fascia by electrical cautery under direct vision. As the dissection progresses, retractors of escalating sizes are used to maintain the space. The dissection progresses until the sternocleidomastoid muscle is reached, upon which, the medial aspect of the muscle is exposed [12] and the soft tissues overlying it are elevated from the sternal notch [11]. The dissection advances between the sternal and clavicular heads and a retractor is used to elevate the sternal heads to expose the strap muscles and identify the omohyoid muscle [11]. The dissection is continued beneath the strap muscles exposing the thyroid gland [24].

Maintenance of Space

The space is maintained using the Chung retractor [14, 25] [22/47 cases (46.80%)] or the Kuppersmith robotic thyroidectomy retractor (Marina Medical, Sunrise, Fla., USA) [11, 25] [25/47 cases (53.19%)]. The retractor system is attached to the operating table on the contralateral side of the patient.

Docking

The da Vinci robot cart is positioned on the contralateral side of the patient and the robotic arms are introduced into the space created by the retractor. Three arms are inserted into the space to control three instruments (Harmonic Shears, Ethicon, Somerville, N.J., USA), Maryland Dissector (Intuitive Surgical Inc.) and Pro-Grasp Forceps (Intuitive Surgical Inc.) and the endoscope, which is positioned centrally using a 30-degree camera aimed dorsally [24]. The instruments are positioned in an inverse triangle.

Table 1. Patient age distribution (mean age 43.17 ± 13.58 years, range 20–80 years)

Age, years	Number of patients (%)
<10	0
11–20	1 (2.17)
21–30	7 (15.22)
31–40	15 (32.61)
41–50	10 (21.74)
51–60	7 (15.22)
61–70	4 (8.70)
71–80	2 (4.35)

Robotic: Total Thyroidectomy

During the robotic portion of the procedure, the surgeon is positioned away from the patient at the work station. The operation proceeds in a similar fashion to open thyroidectomy [12].

Closure

Upon completion, the robotic instruments are removed and ropivacaine is administered along with the positioning of a Blake drain. The axillary wound is then closed.

Results

When 'n =' is cited, this refers to the total sample size.

Patient Characteristics

Forty-six patients underwent 47 procedures (1 right-sided lobectomy followed by a left-sided totalization). The average age was 43.17 ± 13.58 years ($n = 46$, range 20–80) (table 1) and male/female ratio was 1:22 (2:44 patients). The average body mass index (BMI) was 21.76 ± 3.77 ($n = 46$, range 15.24–40.56).

Results of Preoperative FNA

Forty patients (86.96%, $n = 46$) underwent preoperative laryngoscopy and all underwent preoperative FNA. Preoperative FNA found 10 colloid lesions (21.28%, $n = 47$), 23 follicular lesions (48.93%, $n = 47$), 12 lesions suspicious for papillary thyroid cancer (25.53%, $n = 47$), 1 confirmed papillary thyroid cancer (2.13%, $n = 47$) and 1 nondiagnostic (2.13%, $n = 47$). The ratio of malignant to benign disease was 1:33, in addition to the 12 lesions suspicious for malignancy.

Final Pathological Results

The final pathological report contained 6 follicular lesions (13.04%, $n = 46$), 24 follicular adenomas (52.17%,

Table 2. Breakdown of time taken for different surgical procedures

Type of operation	Total time, min	Working-space time, min	Docking time, min	Console time, min
Lobectomy (n = 30)	136.63±38.12	37.73±14.02	19.20±7.10	56.07±20.21
Subtotal thyroidectomy (n = 3)	174.0±25.36	49.0±13.86	34.33±5.86	64.0±9.17
Total thyroidectomy (n = 12)	146.12±25.72	38.0±7.48	25.50±16.86	62.13±14.54
Totalization (n = 1)	86.0	29.0	11.0	42.0

n = 46), 3 colloid lesions (6.52%, n = 46), 1 thyroiditis/lymphatic lesion (2.17%, n = 46), 3 adenomatoid lesions (6.52%, n = 46), 3 oncocytic adenomas (6.52%, n = 46), 3 papillary cancers (6.52%, n = 46) and 3 microcapillary cancers (6.52%, n = 46). The ratio of malignant to benign disease was 1:6.67.

Specimens Produced

Thirty-three procedures (70.21%, n = 47) produced unilateral specimens and 14 (29.79%, n = 47) produced bilateral specimens. The average unilateral specimen size was $43.69 \pm 24.92 \text{ cm}^3$ (range 5–112, n = 33). In bilateral specimens, the right-sided average was $54.68 \pm 30.02 \text{ cm}^3$ (range 12–112, n = 14) and the left-sided average was $40.16 \pm 36.16 \text{ cm}^3$ (range 24–160, n = 14). The overall average individual specimen size was $45.40 \pm 28.95 \text{ cm}^3$ (range 5–160, n = 47). The overall average volume of thyroid tissue removed was $58.92 \pm 38.9 \text{ cm}^3$ (range 5–200, n = 47). For benign lesions, the average was $60.78 \pm 39.20 \text{ cm}^3$ (range 5.0–200, n = 40) and for malignant lesions, it was $40.30 \pm 31.65 \text{ cm}^3$ (range 8–85, n = 7). The average largest diameter of lesions resected was $3.72 \pm 0.95 \text{ cm}$ (range 1.4–6.0, n = 47). For benign lesions, the average was $3.84 \pm 0.9 \text{ cm}$ (range 2.5–6, n = 40) and for malignant lesions, it was $3.06 \pm 1.04 \text{ cm}$ (range 1.4–4, n = 7).

Nineteen of the cases had multiple loci of pathology (40.43%, n = 47). Four procedures provided samples with parathyroid glands (8.51%, n = 47).

Extent of Surgery

Thirty lobectomies (63.83%, n = 47), 3 subtotal thyroidectomies (6.38%, n = 47), 13 total thyroidectomies (27.66%, n = 47) and 1 totalization (2.13%, n = 47) were performed. In terms of benign lesions, there were 27 lobectomies (67.5%, n = 40), 3 subtotal thyroidectomies (7.5%, n = 40) and 10 total thyroidectomies (25.0%, n = 40). In terms of malignant disease, there were 3 lobectomies (42.86%, n = 7), 3 total thyroidectomies (42.86%, n = 7) and 1 totalization (14.29%, n = 7).

Surgical Procedure

Twenty-seven cases were performed from the right side (57.54%, n = 47) and 20 from the left (42.55%, n = 47). One patient underwent right-sided lobectomy followed by left-sided totalization. One case was converted to an open procedure (2.13%, n = 47) due to the large size and hemorrhagic characteristics of the tumor. On FNA, the lesion was described as an oncocytic tumor, and specimen analysis revealed it to be a vesicular-form papillary cancer. No cases required a chest port.

Timing

Total operative times were recorded for all procedures; however, for one procedure only the total operative time was recorded (case omitted from subsequent analysis of timing). See table 2.

Complications

There were 9 postoperative complications (19.15%, n = 47), 5 (55.56%) of which were RLN injuries [10.64% of all procedures (n = 47)]. Four of these 5 (80%, i.e. 8.52% of all procedures) were transient and were resolved in 3, 8, 7 and 4 weeks, respectively; the other 1 (20%, i.e. 2.13% of all procedures) was permanent. There were 2 brachial plexopathies diagnosed using electromyography (4.26%, n = 47), which resolved in 3 and 8 weeks, respectively. There was 1 postoperative hematoma and 1 patient reported postoperative dysphagia. There were no cases of postoperative hypocalcemia or intraoperative complications (intraoperative hemorrhage $>50 \text{ cm}^3$, tracheal or skin injury). Thirty-eight patients reported dysesthesia over the working space (80.85%, n = 47), on average lasting 3 ± 1.14 weeks (range 2–6, n = 38).

Hospital Stay

The average hospital stay was 3.22 ± 1.11 days (range 3–10 days, n = 47). Two patients stayed more than 3 days (i.e. 6 and 10 days, respectively), both due to pulmonary artery thrombosis requiring anticoagulation therapy.

Follow-Up

The average length of follow-up was 7.29 ± 7.03 months (range 1–24 months, $n = 46$) and there were no cases of disease recurrence. The postoperative thyroglobulin levels for the 3 cases of papillary carcinoma were 0.24, 0.21 and 0.22 ng/ml, respectively.

Forty-five (91.11%) of the patients had a normal voice at 6 weeks after surgery and 1 patient who was followed up at 4 weeks also had a normal voice. Forty-six patients underwent postoperative laryngoscopy and 42 (91.3%) were found to be normal. Of the 4 abnormal cases, 1 was found to have an abducted left vocal cord and had RLN weakness which resolved in 7 weeks. The second had a palsy of the left vocal cord which resolved in 8 weeks. The third had right vocal cord weakness which resolved in 3 weeks and the fourth had a paralyzed left vocal cord which was found to be permanent.

Discussion

Robotic thyroid surgery has been shown to be effective in the management of thyroid cancer [10, 12–15] and to match open [10] and endoscopic techniques in terms of patient safety [15]. Despite this, there has been no large-scale uptake of the procedure. Before robotic thyroid surgery becomes universally accepted, it is imperative to define pathological states and patient characteristics for use as indications to ensure the best possible outcomes.

A literature search was undertaken on PubMed (October 2012) using the key words ‘robotic transaxillary gasless thyroid’. This search produced 23 results from 2009 to the present; 7 were excluded, but 16 contained data which form the basis of the following discussion (online suppl. tables 1, 2).

Anatomical Considerations

The transaxillary approach to total thyroidectomy brings with it some inherent anatomical problems for dissection of the contralateral lobe, in terms of visualization of the RLN and parathyroid glands [11]. North American surgeons, subjectively, found it more difficult to identify the vital structures; however, with practice, this was improved [11]. It can be overcome by tilting the endoscope or the operating table [10].

Patients with a substernal or retropharyngeal goiter and lesions in the dorsal thyroid area near to the tracheo-oesophageal groove [12, 14, 15, 26–30] were excluded from previous studies [16], suggesting that careful patient

selection in terms of anatomical lesion location is paramount to successful outcomes.

Malignant Disease

In the management of malignant thyroid disease, oncological safety and the extent of dissection must be paramount [10]. The literature comparing open to robotic techniques has shown that for 266 patients (192 operated on robotically) in South Korea with papillary thyroid carcinoma, there was no difference in postoperative thyroglobulin levels and no disease recurrence over a period of 29.1 months [10]. It can thus be concluded that robotic thyroidectomy is a safe alternative to open thyroidectomy in patients with papillary thyroid carcinoma [10]. Our average follow-up period was 7.29 months, during which there was no disease recurrence. Postoperative thyroglobulin levels for the 3 cases of papillary cancer were below the recommended limit of 10 ng/ml, suggestive of a good outcome following thyroidectomy [31]. The literature also shows that the robotic technique has been utilized in the management of follicular [11, 15, 32], medullary [33] and microcapillary [20, 34] carcinoma (online suppl. table 1).

In the literature, the sizes of neoplasm indicated for this approach range from well-differentiated or papillary thyroid carcinoma <2 cm [12, 15, 27, 29, 30, 33] to any malignant nodule <6 cm [35]. In terms of the size of tumor removed during surgery, this ranges from 1.0 to 60.0 mm [12, 30, 35]. The results from our own data support this as tumors ranging from 14 to 50 mm were resected (average 32.4 mm). We hold the view that malignant disease should be limited to 20–40-mm tumors; however, as is evident from the literature and from our own practice, there have been instances of larger-sized neoplasms being resected.

Extrathyroidal involvement [12, 14, 15, 20, 26, 27, 29–33], multiple lateral lymph node involvement [12, 14, 15, 27–30, 34], perinodal involvement at metastatic lymph nodes [12, 14, 15, 20, 27–30, 34] and distant metastatic disease [12, 14, 26–33] have all been cited as exclusion criteria for studies (online suppl. table 2). However, a South Korean team with experience of over 1,400 robotic thyroidectomies has included more advanced papillary thyroid carcinoma or lateral neck node metastases [10]. In addition, they have performed procedures managing invasion of the trachea or RLN [10], suggesting that the procedure is applicable to more advanced disease. Another study also included patients presenting with one or two minimal lateral neck metastatic lymph nodes [20], suggesting that robot-assisted modified radical neck dissection (MRND) for the management of lateral neck node

metastases is feasible and safe. It is evident, therefore, that in the future, the indications for robotic thyroid surgery may be extended to include advanced thyroid cancer [30].

Benign Disease

The robotic technique has been previously indicated for colloid lesions [33], multinodular goiters [33], follicular adenomas [11, 34, 35] and benign hyperplastic [35] and adenomatoid nodules [11]. Many studies limit size to <5 cm [12, 15, 30, 33], but in terms of the actual specimens removed, there is a range of 10–72 mm [16]. In our own data, we removed benign lesions ranging from 25 to 60 mm in size (average 38.4 ± 9 , $n = 40$). It is our view that benign disease can be included up to 6 cm, bearing in mind the size of the contralateral lobe during total thyroidectomy.

Evidence recommends total thyroidectomy as the most appropriate management of Graves' disease [36]. Endoscopic approaches are not recommended due to difficulties in controlling bleeding [23, 37]. In a series of 5 robotic subtotal thyroidectomies for Graves' disease, there were no conversions to open or endoscopic techniques and no postoperative complications (e.g. bleeding, hypocalcemia and vocal cord palsy) [23]. Importantly, the case series cited lower intraoperative blood loss than with endoscopic and open techniques, attributed to the excellent surgical field view and precise movements when using the robot [23]. This suggests that the robotic approach is feasible in patients with Graves' disease and should be looked upon as an alternative to traditional open or endoscopic techniques.

Patient Selection

The importance of careful patient selection cannot be underestimated [19]. Patient characteristics have been used as exclusion criteria for this procedure in both benign and malignant disease include thyroiditis, as both a definite and relative contraindication [32, 33], severe [12, 14, 15, 27, 29] or advanced Graves' disease [16, 26] and a history of neck surgery [12, 14–16, 26, 27, 29]. Graves' disease, however, has since been shown to be a valid indication for the technique [23].

The transaxillary robotic approach has a distinct advantage over open surgery including subjective satisfaction with scar cosmesis [16, 29], suggesting it to be appropriate for patients with 'esthetic concerns or known challenges to wound healing' [24]. This may suggest an increased benefit in North American populations due to the diverse ethnicity and potential for keloid scar formation [38, 39].

The robotic approach was originally described in Korea [13], and concerns have been voiced regarding selecting patients from other populations due to differences in BMI and body habitus [38]. Despite these concerns, it has been shown that the trend to a longer operative time for patients with higher BMIs is not significant [38], although surgeons have indeed reported the surgery to be more difficult in patients with higher BMIs [11]. To overcome these technical difficulties, adjustments to the surgical procedure have been made such as the modified ipsilateral arm position [11, 21], the introduction of brachial plexus monitoring [40, 41] and the use of the Kupper-Smith robotic thyroidectomy retractor (Marina Medical) [11, 25] rather than the Chung retractor [14, 25].

Complications

Research has found no significant difference in intraoperative and postoperative complications between open and robotic thyroidectomy [10]. We report one permanent RLN injury (2.13% of the cases) which is comparable to results from South Korea of 192 robotic thyroidectomies (where 2% of the patients suffered permanent RLN injury) and 266 open thyroidectomies (where none of the patients suffered permanent RLN injury) [10]. We also report one postoperative collection of blood, whereas in South Korea hematoma evacuation was seen only in the open group [10]. Our results show no cases of postoperative hypocalcemia, whereas in South Korea, after 90 open thyroidectomies, 3% of patients had permanent hypocalcemia [10].

Complications seen only in the robotic transaxillary approach include dysesthesia over the working space, reported in 80.48% of patients in our series; all cases, however, resolved on average within 3 ± 1.14 weeks. In addition, we had 2 cases of brachial plexopathy, both of which resolved and occurred early in the case series, most likely related to variations in BMI and body habitus not seen in populations previously studied in South Korea. Subsequent to these 2 cases, modifications to the arm position [11] and additional brachial plexus monitoring ensured no other cases were reported.

Conclusion

The transaxillary robotic approach to thyroid surgery is fast becoming a viable alternative to open or endoscopic methods and has been predicted to become the standard technique for thyroid surgery in the future. The indications for this technique are continually ex-

panding. It has been shown to be efficacious in the management of thyroid cancer with lateral neck metastases; however, more data is required relating to oncological safety in long-term follow-up. Benign thyroid disease is also appropriate for this intervention, including the previously excluded Graves' disease. Furthermore, careful patient selection is fundamental to achieve consistently successful results, especially with the geographical expansion to North America and Europe. The excellent cosmetic results of this procedure make it ideal for pa-

tients who have esthetic concerns or particular difficulties with healing. As with all new surgical procedures, further evidence should be sought to confirm its indications over time.

Disclosure Statement

None.

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