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Review Article

Evolution of transoral endoscopic thyroidectomy vestibular approach according to the IDEAL framework

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Abstract

Background: The IDEAL Framework is a scheme for safe implementation and assessment of surgical innovation. The transoral endoscopic thyroidectomy vestibular approach (TOETVA) is a new innovation in thyroid surgery that eliminates the need for a cervical incision. Despite considerable interest and adoption worldwide, significant scepticism remains regarding the outcomes and cost-effectiveness for healthcare systems. The aim of this narrative review was to appraise the available literature and examine whether TOETVA has progressed in line with the IDEAL Framework.

Methods: A literature review of PubMed with a focus on historical and landmark studies was undertaken to classify the evidence according to the different stages of the IDEAL Framework.

Results: Several different transoral approaches were developed by a small of number of surgeon-innovators on animals and cadavers, and subsequently in first-in-human studies. The trivestibular approach emerged as the safest technique, with further refinements of this technique culminating in TOETVA. The basic steps and indications for this technique have been standardized and it is now being replicated by early adopters in many centres worldwide. The development of TOETVA has closely aligned with the IDEAL Framework, and is currently at stage 2B (Exploration).

Conclusion: There is need for multi-institutional collaborations and international registry studies to plan high-quality randomized trials comparing TOETVA with other remote-access approaches and collect long-term follow-up data. In countries where TOETVA has yet to be adopted, the IDEAL Framework will be a useful roadmap for government regulators and professional societies to evaluate, regulate, and provide best practice recommendations for the adoption of this technique.

Introduction

The IDEAL Framework and Recommendations is a paradigm first proposed in 2009 that describes the stages of evolution in the life cycle of surgical innovation, and provides the basis for reporting and evaluating new surgical techniques[1]. It consists of a five-stage roadmap (Idea, Development, Exploration, Assessment, and Long-term study) to translate a new surgical innovation from an idea to safe implementation, with emphasis on prospective observational studies and high-quality RCTs. This framework is increasingly being adopted by government regulators, funding agencies, and professional bodies as a standard for evaluation, development, and dissemination of surgical innovation within healthcare systems.

A recent innovation in the field of thyroid surgery is the development of the transoral endoscopic thyroidectomy vestibular approach (TOETVA), with the goal of avoiding a cervical scar. This ‘scarless’ technique represents the next frontier in the progress of thyroid surgery, which has evolved over the years from a procedure with high mortality to a safe and highly standardized operation. Although TOETVA has generated considerable interest and adoption worldwide, significant scepticism remains regarding outcomes and cost-effectiveness for health systems. Whether the development of TOETVA has aligned with steps and recommendations of the IDEAL Framework has hitherto been unknown.

This article reviews the evidence base, including landmark studies in the field of transoral endoscopic thyroid surgery as it progresses from the pre-IDEAL phase through the various stages of the IDEAL Framework, and assesses whether the evolution of TOETVA has aligned with this framework. Moreover, it examines whether gaps exist in the current life cycle of this surgical innovation, and provides a roadmap for innovators, early adopters, and the early majority of surgeons to move the field of TOETVA forwards in line with the IDEAL paradigm.

TOETVA was first reported in 2016, yet the genesis of this technique has its roots in earlier work by a small number of surgeon-innovators. *Figure S1* shows the evolution of the literature on transoral thyroidectomy based on the studies covered in this review and the geographical location of the authors. Studies include not only TOETVA, but also earlier iterations of the transoral technique, the sublingual, and combined sublingual and vestibular approaches. There has been a rapid increase in the number of clinical studies on TOETVA in recent years from many countries worldwide, so only a selected number of studies is included in this review. The following

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sections of this article describe how these studies have evolved according to the stages of the IDEAL Framework: stage 0 (Pre-IDEAL), 1 (Idea), 2A (Development), 2B (Exploration), 3 (Assessment), and 4 (Long-term studies).

Stage 0: Pre-IDEAL

The pre-IDEAL stage is the preclinical phase in which the feasibility of a surgical innovation is first tested and developed on cadavers and animals. Early experimental work on transoral endoscopic thyroidectomy revolved around a number of different transoral approaches to the anterior neck (*Fig. S1*). The first of these, based on a sublingual access, was reported by Witzel and colleagues[2] in 2008. They used a single 10-mm sublingual trocar and two 3.5-mm trocars at the external neck to access the thyroid gland in fresh cadavers and living pigs. Karakas and co-workers[3] refined this technique using a single paralingual incision with a modified rigid rectoscope (oraloscope) to perform hemithyroidectomies on cadavers and living pigs. The narrow access via the rigid oraloscope, however, meant that it was more suitable for parathyroidectomy than thyroidectomy.

The second transoral method, a combination of sublingual and oral vestibular approaches, was first reported by Benhidjeb *et al.*[4] from the New European Surgical Academy (NESA) collaborative group using human cadavers, after extensive studies on the anatomy of the floor of mouth and cervical spaces of cadavers[5] and living pigs[6]. This combined method used a three-point access with a 5-mm optical port at the floor of the mouth for the endoscope and two 3-mm working ports at the oral vestibule beneath the mandibular incisors bilaterally, and creating a subplatysmal working space using low-pressure carbon dioxide insufflation[5].

Richmon and colleagues[7] initially employed the combined sublingual and oral vestibular approach to perform robot-assisted transoral thyroidectomy in human cadavers. The limitations encountered with the sublingual approach using the robot led them to move the optical port to the oral vestibule, thus creating the first entirely oral vestibular approach[8]. This technique employed three ports under the vestibule—a central 10-mm endoscopic port and two 5-mm working ports for instruments on both sides of the central port—and was hence termed the trivestibular approach. Park *et al.*[9] further demonstrated the feasibility of performing central lymph node dissection alongside total thyroidectomy using this trivestibular transoral route in cadavers.

Stage 1: Idea

Stage 1 comprises the first-in-human studies, when a small pioneering group of surgeons, defined as innovators, start performing the new surgical procedure on a few highly selected patients and report the outcomes in the form of case series. The first transoral technique to progress to first-in-human studies was the combined sublingual and oral vestibular approach. Although this approach was shown to be feasible in cadavers and porcine models, the NESA group[10] decided not to proceed with clinical application owing to safety concerns posed by the limited size of the floor of mouth and narrower neck in humans. Nonetheless, Wilhelm and Metzig[11] reported their first-in-human case with this approach in 2010 and a follow-up prospective case series[12] of eight patients, with relatively high rates of complications such as paraesthesia of the mental nerve (seven of eight patients), conversion to open surgery (three of eight patients), transient recurrent laryngeal nerve palsy (two of eight patients), permanent recurrent laryngeal nerve palsy (one of eight patients), and local infection at the vestibular incision site (one of eight patients).

Similar difficulties were encountered by Karakas and co-workers[13] when performing a gasless single paralingual incision technique, termed transoral partial parathyroidectomy (TOPP), on two patients with parathyroid adenoma, resulting in hypoglossal nerve injury in one patient. High complication rates in a follow-up prospective case series of five patients, and poor patient acceptance led this group to abandon further work on the technique[14].

The first application of an entirely oral vestibular approach in humans was reported in a prospective series of eight patients by Nakajo *et al.*[15] in 2013, using a single 2.5-cm incision at the centre of the oral vestibule, and a gasless approach to create a working space using Kirschner wires to lift up the anterior neck skin. In this series, one patient experienced recurrent laryngeal nerve palsy but none had mental nerve injury. Meanwhile, the first-in-human application of the trivestibular technique for endoscopic thyroidectomy was reported by Wang and colleagues[16]. In a cohort of 12 patients undergoing this procedure, called the endoscopic thyroidectomy via oral vestibular approach (ETOVA), there were only two instances of transient skin ecchymosis with no recurrent laryngeal nerve or mental nerve injury[16].

Stage 2A: Development

Stage 2A focuses on the technical development and feasibility of the surgical innovation in an initial small and selected group of prospectively recruited patients in single institutions, and reporting of short-term clinical, technical, and safety outcomes. As shown in *Fig. S1*, the oral vestibular technique entered this phase in 2015 when Wang and colleagues[17] reported a larger cohort of 41 patients who underwent ETOVA, with two cases of lower jaw skin ecchymosis, one of skin piercing, one of anterior skin burn, and one of transient recurrent laryngeal nerve palsy. Anuwong[18] subsequently made further technical refinements to the vestibular technique, and published a prospective case series of 60 patients using this technique, named TOETVA, with safe outcomes. In this series, there were only two instances of transient hoarseness, one of late postoperative haematoma, and no mental nerve injury or infections.

In contrast, there was lack of progress on the sublingual approaches at this stage. No further work beyond stage 2A has been published by Karakas and colleagues on their entirely sublingual TOPP technique. There were two further reports on the combined sublingual and vestibular technique: a case series[19] of 96 patients from two institutions, and a further case series[20] of 81 patients. In both series, there were significant numbers of patients with postoperative complications, including permanent recurrent laryngeal nerve injury, mental nerve injuries, and anterior neck infections. Since then, there have been no further studies on this transoral approach.

Stage 2B: Exploration

In this stage, there is a shift of focus from technical development towards achieving a greater experience of the procedure in a wider group of surgeons and patients. The aim of this phase, akin to bridge to a pivotal trial, is to collect information on safety and short-term clinical outcomes through collaborative multicentre prospective cohort studies, to determine whether and how to progress to a definitive comparison against the current best treatment[1].

With favourable outcomes in stage 2A, TOETVA emerged as the preferred transoral procedure, and the fundamental steps of this technique established by Anuwong permitted replication in other centres. TOETVA entered stage 2B (Exploration) when Udelsman *et al.*[21], in collaboration with Anuwong, published the first case series of TOETVA outside Asia. This consisted of five patients with no postoperative complications, suggesting that the technique is also applicable to Western patients with generally larger body habitus than Asians.

The Transoral Neck Surgery (TONS) Study Group was established at the First International Thyroid Natural Orifice Transluminal Endoscopic Surgery Conference in Bangkok, Thailand, in 2016 to standardize and refine the TOETVA technique[22]. This group, led by Anuwong, reported the first large cohort study[22] of 200 consecutive patients who underwent TOETVA at a single institution in Bangkok, further underscoring the safety and feasibility of TOETVA with a reasonable duration of surgery, minimal pain scores, and low complication rates (4.0 per cent transient hoarseness, 17.5 per cent transient hypoparathyroidism, 1.5 per cent transient mental nerve injury, with no permanent damage to the nerves or parathyroids). They also described the indications and contraindications for TOETVA in this report, mainly centred around patient preference and thyroid size respectively, and made further refinements to the position of the ports to avoid injuring the mental nerve[22].

Since then, several early adopters worldwide have published initial experience and early outcomes of TOETVA. These include groups from South Korea[23–27], China[28,29], USA[30,31], Italy[32], Germany[33], France[34], Mexico[35,36], Brazil[37,38], Israel[39], and Vietnam[40–43] (*Fig. S1*). Minor modifications of the technique have been reported for the creation of working space, including use of a hybrid space-maintaining system[28], or a specially designed retractable blade[44], although low-pressure carbon dioxide insufflation remains the most widely used approach. To mitigate the risk of injury to the recurrent laryngeal nerve, some studies[30,32,45] have incorporated intraoperative nerve monitoring into TOETVA. Larger single-centre series with several hundreds of patients have also been reported by groups in Thailand[46], USA[45], South Korea[27], and Vietnam[47]. The largest among these was by Anuwong and colleagues[46], who reported a retrospective series of 425 TOETVA procedures, and compared the outcomes with those of 216 open thyroidectomies using propensity score matching. TOETVA had significantly longer operating times, but the overall rate of complications (hypoparathyroidism, transient recurrent laryngeal nerve palsy, seroma, and haematoma) was comparable in the two groups.

An important feature of stage 2B is the development of a consensus on patient selection for a new surgical technique. The first set of recommendations for TOETVA patient selection was published by the TONS Study Group[22] in 2017, which included patient motivation to avoid a neck scar, thyroid lobe size less than 10 cm, benign tumours, follicular neoplasm, papillary microcarcinoma, and Graves' disease. Since then, with greater experience in the adoption of TOETVA, the selection criteria have been expanded to include patients with benign or indeterminate nodules no larger than 6 cm, or differentiated thyroid carcinoma nodules no larger than 2 cm, but excluding those with a large substernal goitre, lymph node or distant metastasis, extrathyroidal extension, and a history of previous neck surgery or irradiation[48,49]. Using these selection criteria, a study[50] of 1000 consecutive patients who underwent thyroid or parathyroid surgery across three academic medical centres in the USA over 3 years found 55.8 per cent of these patients to be eligible for transoral surgery. A similar single-centre study[51] from Turkey of 1197 consecutive patients who underwent thyroid surgery over 3 years found that 42.8 per cent were suitable for TOETVA. An important caveat, however, in these studies was that patient preference was not considered. It is likely that patient preferences, shaped by patients' perception of the safety of TOETVA and the sociocultural stigma of a neck scar, will influence the adoption and uptake rates of TOETVA. A corollary to these findings is that, outside centres with high annual caseloads of thyroid surgery, a new surgeon may have difficulty performing enough procedures to complete the learning curve within a reasonable time.

Other considerations during stage 2B are training, preceptorship, and learning curve evaluation as TOETVA is adopted by an increasing number of surgeons. So far, there is no agreed training curriculum or formalized training programme for TOETVA. A number of early adopters of this technique have outlined the minimum requirements for surgeon candidacy before learning TOETVA. An aspiring TOETVA surgeon should be a high-volume thyroid surgeon proficient in procedures of the central neck[52,53], and be familiar with either laparoscopic or endoscopic surgery. Emerging retrospective data suggest that the learning curve is somewhere between 11 and 15 procedures[38,54], although a larger learning curve of 25–30 operations has been reported for otolaryngologist—head and neck surgeons without previous experience in robotic or laparoscopic surgery[39]. Several recommendations have been published on how aspiring TOETVA surgeons should map their professional development and involvement with this technique[52,53]. These include the need to undertake a literature review and observe procedures performed by TOETVA experts, before undertaking formal training through a transoral surgery course, practising on at least one or preferably two cadavers[52,53]. TOETVA training courses that include didactic lectures and dissection on cadaveric models are available in several countries. Subsequently, new TOETVA surgeons should also have a preceptor during their initial learning curve and review their surgical outcomes over time[52,53].

Stage 3: Assessment

The evolution of TOETVA has yet to reach stage 3, where the effectiveness of a new technique is assessed against current standards using properly conducted high-quality RCTs. Although a number of studies[26,29,35,38,46,55–57] in the earlier IDEAL stages compared the outcomes of TOETVA against those of open thyroidectomy and other remote-access thyroidectomy techniques (transaxillary[58], robotic facelift[58], and areolar[59] approaches), these were retrospective. To validate the efficacy and safety of TOETVA in stage 3, it would be necessary to conduct large RCTs comparing TOETVA against the appropriate standard of care using outcome measures identified during stage 2B, such as perioperative outcomes, short- and long-term complications, and oncological and functional results.

So far, there has been no RCT comparing the effectiveness of TOETVA *versus* open thyroidectomy. The considerations and challenges in designing RCTs comparing TOETVA with open thyroidectomy have been discussed[60]. In particular, the low rates of complications in open surgery make it challenging to design a superiority or equivalence trial, and a non-inferiority trial design has therefore been suggested[60]. Furthermore, the appropriateness of conducting RCTs to compare open thyroidectomy with TOETVA is a point of contention. The primary advantage of TOETVA is avoidance of a visible neck scar. Therefore, if a patient is strongly motivated to avoid such a scar, it would be inappropriate to randomly assign the patient to undergo open thyroidectomy and expect the patient satisfaction and quality-of-life scores to be equivalent to those after TOETVA. Instead, a more suitable comparison might be between TOETVA and other remote-access thyroidectomy approaches in a large RCT. There is currently no published large RCT comparing TOETVA with other remote-access approaches. It is worth noting that Wang and colleagues in stages 1 and 2B designed small RCTs comparing ETOVA with endoscopic thyroidectomy via the areolar approach (12[16] and 41[17] patients per treatment arm). Both studies reported increased patient satisfaction with ETOVA, whereas other surgical outcomes and postoperative complications were comparable between treatment arms[16,17] Nonetheless, these two studies do not meet the requirements of stage 3 because of their small sample size.

To circumvent the barriers towards achieving large patient numbers in an RCT for TOETVA, a number of strategies have been proposed. These include the use of international multicentre trials, international registries such as the TOETVA Collaborative Module of the American Association of Endocrine Surgeons Collaborative Endocrine Surgery Quality Improvement Program, and expertise-based trials that allow participating surgeons to treat eligible patients using their preferred intervention, minimizing the influence of learning curve[60].

Stage 4: Long-term studies

Beyond the Assessment stage, TOETVA will also need to be assessed for long-term outcomes. For TOETVA to gain widespread acceptance by surgeons and patients, it should provide better quality of life for patients while demonstrating equivalent surgical and oncological outcomes to the standard, which is open thyroidectomy. The use of international registries will not only allow assessment of early outcomes from large patient cohorts, but also provide data for learning curve analysis, and oncological and functional outcomes.

Discussion

The aim of this article was to describe the evolution of TOETVA, guided by the IDEAL paradigm of surgical innovation. TOETVA was born from the idea that the transoral route provided a means to access the thyroid gland and evolved as a leading 'scarless' approach. In the pre-IDEAL phase, several different transoral approaches were developed by a small of number of surgeon-innovators on animals and cadavers. Among the techniques that progressed to first-in-human studies, the trivestibular approach emerged as the safest, with further refinements of this technique culminating in TOETVA. Standardization of the technique, and establishing a framework for surgeon candidacy, patient selection, and institutional support has permitted its replication in other centres around the world.

The IDEAL Framework has not been used so far within the field of thyroid surgery. Although TOETVA was not initially planned according to this framework, the evolution of this technique has largely followed this paradigm rather closely and is currently at stage 2B (Exploration). The basic steps and indications for this technique have been standardized by a small group of innovators and are now being replicated by early adopters in many centres around the world. Although the IDEAL Framework emphasizes the evaluation of new techniques prospectively, many studies on TOETVA are retrospective in nature, and a few stage 2A studies reported patient numbers that greatly exceeded the typical number expected of studies in this stage. A limitation of this article is that the overview is subject to the authors' personal interpretation of how the evolution of TOETVA has aligned with the IDEAL Framework.

The main drive behind TOETVA from the patient's point of view is to avoid a visible neck scar. Randomization of such patients to a 'scarless' approach *versus* open thyroidectomy would thus be unethical. For TOETVA to move into stage 3, it would be more appropriate to conduct comparative RCTs with other 'scarless' thyroidectomy techniques, such as the facelift and transaxillary approaches. Use of multi-institutional collaboration and data collection would facilitate long-term assessment (stage 4) of the efficacy, outcomes, patient satisfaction with TOETVA, and training standards.

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Supplementary material

Supplementary material is available at *BJS* online.

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