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OTOLOGY: OTOSCLEROSIS AND STAPES SURGERY (JP HARRIS AND A QUESNEL, SECTION EDITORS)

Endoscopic and Robotic Stapes Surgery: Review with Emphasis on Recent Surgical Refinements

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Abstract

Purpose of Review Stapes surgery has been established as the gold standard for surgical treatment of conductive hearing loss in otosclerosis. Excellent outcomes with very low complication rate are reported for this surgery. Recent advances to improve surgical outcome have modified the surgical technique with endoscopes, and recent studies report development of robotical assistance. This article reviews the use of endoscopes and robotical assistance for stapes surgery.

Recent Findings While different robotic models have been developed, 2 models for stapes surgery have been used in the clinical setting. These can be used concomitant to an endoscope or microscope. Endoscopes are used on a regular base regarding stapes surgery with similar outcomes as microscopes. Endoscopic stapes surgery shows similar audiological results to microscopic technique with an advantage of less postoperative dysgeusia and pain. Its utility in cases of revision surgery or malformation is emphasized.

Summary Endoscopic stapes surgery is used on a regular basis with excellent outcomes similar to the microscopic approach, while reducing surgical morbidity. Robotic technology is increasingly being developed in the experimental setting, and first applications are reported in its clinical use.

Keywords Stapes surgery · Robot-assisted stapedotomy · Endoscopic stapedotomy · Otosclerosis · Middle ear surgery · Minimal-invasive surgery

Introduction

Stapes surgery has been widely established as the gold standard for treatment of conductive hearing loss in otosclerosis. The procedure requires a high degree of precision and experience by the performing ear surgeon. A high success-rate, defined by a postoperative air-bone gap of less than 10 dB and low complication rates are described in the literature [1]. Although rare, postoperative complications include vertigo as well as a worsened auditory threshold. Furthermore, a risk of irreversible partial or complete sensorineural hearing loss is reported in 0.7–3% of patients [2]. Alternatively, the hearing loss may be addressed using hearing aids, which should always be proposed during patient counseling [3].

Rosen introduced the surgical treatment in 1952 using an operating microscope [1]. Since then, surgical steps of stapedectomy/stapedotomy have been constant: raising the tympanomeatal flap, lowering the scutum, sectioning the posterior tendon and crura, footplate fenestration, piston placement and crimping, and repositioning the tympanomeatal flap. Surgical difficulties regarding stapes surgery include a small and narrow surgical and visual field. Moreover, even small amounts of bleeding can reduce the visual field impeding the safe and efficient continuation of the operation. Additionally, important anatomical structures close to the oval window, such as the facial nerve, the chorda tympani and ossicles are at risk of iatrogenic damage. To improve the outcome and decrease risk

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of complications, technical modifications were proposed. The most difficult steps requiring extreme precision are the fenestration of the stapes footplate and crimping of the prosthesis. Stapedotomy has shown to have a similar outcome compared to stapedectomy in creating a small fenestra with a mechanical drill or laser [4, 5]. Many different prostheses with differences in material, size, and shape have been developed, including the option of a self-crimping prosthesis [6, 7]. Furthermore, different kinds of lasers have been used increasingly to overcome limitations of mechanical footplate fenestration [8]. It has been well documented that a significant difference of outcome was reported in expert ear surgeons compared to trainees [9].

Endoscopic ear surgery (EES) has gained increasing popularity for all kinds of middle ear surgery in the past years. The main advantage of endoscopes is a better field of view with the possibility of using angled lenses. Regarding stapes surgery, similar outcomes as compared to the microscopic approach have been reported [10].

Robotic surgery nowadays has reached all surgical specialties including middle ear surgery. Its interest relies in exceeding the physical abilities limited by the human hand for improved movement and force accuracy. In the field of microsurgery, such as ophthalmology, neurosurgery, and reconstructive surgery, it has gained increasing attention. Even in experienced surgeons, involuntary gestures such as tremor, jerking, and drifting can occur. Robots have the ability to inhibit these involuntary gestures, resulting in more microsurgical precision, accuracy, and reducing forces applied on other structures [2].

Methods

A comprehensive literature search was conducted on PubMed with the following terms: endoscopic stapes, endoscopic stapedotomy, endoscopic stapedectomy, robotic stapes, robotic stapedotomy, robotic stapedectomy (date of last access: 22.07.2021). Out of 189 screened articles, we selected two types of articles. For endoscopic stapes surgery, only meta-analyses were considered, with a yield of 5 studies. A total of 16 studies were selected for robotic surgery focusing on stapes surgery. We included reports with robots used for experimental and/or clinical use in stapes surgery. One study reported a middle ear surgical robot with clinical application for chronic otitis. Corresponding authors were not contacted. Stapes surgery outcome was measured in means of time, surgical success, and complication rates.

Review and Discussion

Endoscopic Stapes Surgery

EES is becoming more prevalent as a valuable minimal-invasive approach for middle ear surgery. First reported as an adjunct to microscopic surgery, it is now widely used as the main tool for procedures such as tympanoplasty, ossiculoplasty, cholesteatoma resection, and stapes surgery. Fully endoscopic procedures are referred to as "transcanal endoscopic ear surgery" [11], avoiding the need of an external incision (retroauricular, endaural). The microscope remains the appropriate approach for mastoidectomy and the access to the antrum.

Concerning ESS, we reviewed 5 meta-analyses published between 2018 and 2020 comparing the endoscopic vs. microscopic approach as reported in Table 1. The primary outcome of all studies was postoperative auditory gain, usually considered with an airbone-gap of less than 10 dB. The meta-analysis of Fang et al. [12] showed a favorable odds ratio of 1.99 for ESS while other meta-analyses did not show a statistically significant difference. Bone removal, when analyzed, was shown to be significantly reduced in ESS compared to microscopic stapes surgery (MSS) [12, 13]. While Ho et al. [14] reported no differences in manipulation of the chorda tympani in both groups, all other studies show a significant lower injury risk. When analyzed, all studies show lower postoperative dysgeusia in ESS. For secondary outcomes, patient-reported postoperative pain was reduced in the ESS compared to the MSS group in two out of three studies [12, 15••]. Postoperative dizziness and operative time did not show differences in the groups. Other complications were not shown as significant.

Regarding these meta-analyses, endoscopic or microscopic approach for stapes surgery appears to report a similar outcome in terms of postoperative airbone-gap. ESS has the advantage of being a minimal-invasive approach which often requires less bone removal and could result in a reduction of postoperative pain. However, the transcanal microscopic approach using an ear speculum can be considered equal in this regard [16]. As a limitation, measures of postoperative dizziness and pain were reported in different scales between the studies. Subjective symptoms are furthermore influenced by cultural factors and could add a potential bias [15••]. Overall, we must note that most included studies have a retrospective setting and a small sample size. Only 2 randomized controlled studies have been published until now. Audiological outcome can also be biased by use of different kinds and sizes of piston prosthesis [17].

In addition, ESS seems to reduce the risk of chorda tympani injury and consequently postoperative dysgeusia. The benefit of the wide-angled view of the endoscope allows a better visualization which aids in avoiding excessive manipulation of the chorda tympani and potential injury. All middle ear structures are reported to be better viewed endoscopically except for the antrum. The stapes footplate region with its narrow important structures as the facial nerve or ossicles is well seen through the endoscope.

Table 1 List of meta-analyses of endoscopic vs. microscopic stapes surgery

Reference	Country	No. of studies, no. of patients	ESS	MSS	Audiometric outcome of ESS vs. MSS	Bone curetage of ESS vs. MSS	Injury of chorda tympany of ESS vs. MSS	Postoperative dysgeusia of ESS vs. MSS	Postoperative pain of ESS vs. MSS	Postoperative dizziness of ESS vs. MSS	Operative time of ESS vs. MSS
Ho et al. (2021) [14]	USA	12, $n = 585$	269	316	n.s.	-	n.s.	RD −0.152 (CI 95% −0.265–(−0.02))	-	n.s.	n.s.
Fang et al. (2021) [12]	China	12, $n = 673$	298	379	OR 1.99 (CI 95% 1.26–3.13)	OR 0.04 (CI 95% 0.001–0.2)	OR 0.22 (CI 95% 0.11–0.42)	OR 0.21 (CI 95% 0.11–0.41)	OR 0.30 (CI 95% 0.16–0.59)	n.s.	n.s.
Koukkoullis et al. (2020) [34]	Hungary	6, $n = 294$	128	166	n.s.	-	OR 3.51 (CI 95% 1.55–7.93)*	OR 2.36 (CI 95% 1.01–5.51)*	n.s.	n.s.	n.s.
Manna et al. (2019) [15••]	USA	5, $n = 323$	121	162	n.s.	-	RR 0.36 (CI 95% 0.19–0.71)	-	RR 0.27 (CI 95% 0.07–1.02)	n.s.	n.s.
Nikolaos et al. (2018) [13]	Greece	7, $n = 353$	154	199	n.s.	OR 0.01 (CI 95% 0.00–0.007)	-	OR 0.31 (CI 95% 0.14–0.69)	-	-	n.s.

Only statistically significant results are reported. ($p < 0.05$); blanks — not analyzed

ESS endoscopic stapes surgery, *MSS* microscopic stapes surgery, *RD* risk difference, *RR* risk ratio, *OR* odds ratio, *CI* confidence interval, *n.s.* non-significant

*MSS vs. ESS

Equipment required for endoscopic surgery consists of a light source, rigid endoscopes (usually 3-mm diameter, 15-cm length, 0° and 45° angles), a high definition camera, and video screen. The angles of the endoscopes vary depending on surgeons' preferences and patients' anatomy. A 45° or 70° angled-endoscope permits view of hidden recesses such as retrotympanic areas [18]. Advances in imaging technology (e.g., 4K) permit a high-definition image permitting a wide-angled view and enhanced magnification. A better view of the ossicle chain as well as the stapes is beneficial during revision surgery or to detect malformations [11]. While the wide-angled view is a main advantage of the endoscope, small amounts of bleeding can quickly obstruct the field of view and require recurrent cleaning of the scope [19]. To address this issue, the use of cottonoids soaked with epinephrine (1:1000) has shown to provide adequate bleeding control. A further challenge of endoscopic surgery is to rely on a single-handed technique, where the non-dominant hand holds the endoscope. A 2-handed technique has been tried with an endoscope holder or with the help of a robotic arm to hold the endoscope [20, 21•].

Lastly, authors often report the loss of perceptions of depth as an issue in endoscopic surgery. To address this issue, 3D endoscopes have been developed. In our experience, the use of a 3D endoscope did not change the surgical outcome and relies mostly on the surgeon's preference [22]. Operative time mainly depends on the experience of the operating surgeon. Across the literature, no significant difference in operative time between microscopic and endoscopic procedures was reported.

Finally, since EES has been developed at a later stage than microscopic surgery, the learning curve is often reported to be longer. For example, a number of 60 procedures has been reported for a microscopically trained surgeon to change his technique to endoscopic surgery for tympanoplasty [23]. This issue may be overcome by pre-clinical training using an ovine ex vivo model for training EES. The initial model for EES was further refined and validated regarding stapes surgery including the use of laser and has also been shown to be suitable for advanced and salvage procedures [24–26].

Robotic Stapes Surgery

Three types of robots have been reported for stapes surgery: a comanipulated system where the surgeon and the robot hold the tool conjointly; a teleoperated system where the surgeon controls the arm from a distance; and a semiautonomous system where the robot executes a surgical step, passively or actively guided [3]. A summary of robots used in stapes surgery is shown in Table 2. For each robot, all clinical studies and the latest experimental studies were included.

Comanipulated systems have only been used in the experimental setting for stapes footplate fenestration and

placement of a piston prosthesis. Robotical assistance with "Steady Hand" was used for stapes fenestration with a micropick, resulting in reduced force applied to the stapes footplate and improved accuracy for less experienced surgeons [27]. Although with no statistical significance, "Micron" was reported to reduce tremor and accuracy of the fenestration with CO_2 laser [28]. "REMS" was developed to reduce maximum force applied to the incus for prosthesis placement and crimping [29]. One of the main advantages of a comanipulated system is their ease of use, preserving tactile feedback with the ability to reduce tremor, measure force, and avoid involuntary gestures. Less experienced surgeons profited more of robotical assistance than experts.

Teleoperated robot-based systems for middle ear surgery have mostly been reported to execute stapes fenestration or crimping of the prosthesis. Out of the different systems, two devices have been used in the clinical setting. "RobOtol" was designed for middle ear surgery, and particularly for stapes surgery [30]. It is the only device reported to execute all tasks of the operation. Recently, Vittoria et al. published a clinical report of 32 patients successfully operated on with the "RobOtol" as an endoscope or micro-instrument holder [21•]. The robot assistance was used as a laser holder to vaporize the stapedial tendon, posterior and anterior crus and fenestration of the footplate. 9 patients with otosclerosis were successfully treated resulting in a 1-month postoperative airbone gap of $10 + -1$ dB and no intra or postoperative complications. Chorda tympani was preserved in all subjects, with no vertigo, tinnitus, or facial palsy. Therefore, it showed to be a safe device, with a quick learning curve for application. Time of setup of the robot was similar to the microscope; however, operating time was not reported.

The MMS-2 was tested for stapedotomy and prosthesis placement in chronic otitis but had the disadvantage of an insufficient number of degrees of freedom to perform all middle ear procedures [31]. Furthermore, sterilization was an issue. Although developed for stapedotomy, MMS-2 was only used in the clinical setting for chronic otitis through placement of TORP and PORP prostheses [32]. To our knowledge, it has not been used for clinical stapes surgery. Although being less user-friendly, teleoperated systems achieve more tremor suppression, improve motion control accuracy and motion scaling with a broader angle of movement.

One autonomous-semiautonomous system was developed as an automatic micro-drill for the stapes footplate with an accuracy of up to 0.02 mm. In our experience, we successfully developed and used an autonomous robotic system for middle ear access for cochlear implantation in 9 patients [33]. While the procedure was safely done, it was more time-consuming and labor-intensive. Further developments for refinements and optimization of work flow are ongoing.

Although still in a mostly laboratory setting, recent advances and a few clinical studies show growth and advances in robotics for middle ear surgery. Technical tasks could be performed with robot assistance increasing the accuracy of movement and higher control of force. Moreover, these robotic assistances usually take up a lot of volume in the confined space of the operating room. While their use shows a growing interest, there are still limited data in the clinical application with no proof of reduced rates of complications or better surgical outcome. In the field of endoscopic sinus surgery, the "iArmS" robotic armrest has been developed and used in the clinical setting. It was reported to reduce the lens cleaning interval potentially reducing operating time [20]. Research and development and use of robotic assistance require financial investments with costly devices. Actually, no clear advantage of robotic surgery showed a better outcome of a reduced operating time [3].

Table 2 List of reported robots for stapes surgery

Robot type	Reference	Country	Robot name	Setting	Tasks
Comanipulated	Razavi et al. (2019) [29]	USA	REMS	Experimental	Prost,Crimp
	Vendrametto et al. (2015) [28]	Italy	Micron	Experimental	Stap
	Rothbaum et al. (2002) [27]	USA	Steady Hand	Experimental	Stap
Teleoperated	Vittoria et al. (2021) [21•]	France	RobOtol	Clinical	All
	Miroir et al. (2012) [30]	France	RobOtol	Experimental	All
	Strauss et al. (2012) [32]	Germany	MMS-2	Clinical	Prost*
	Peschka et al. (2015) [31]	Germany	MMS-2	Experimental	Stap
	Yasin et al. (2016) [35]	USA	Prototype custom	Experimental	Prost
	Bell et al. (2012) [36]	Switzerland	Robotics Department NTB	Experimental	Crimp
	Runge et al. (2011) [37]	Germany	TUM Mikromanipulator	Experimental	Stap
Semiautonomous	Brett et al. (1995) [38]	United Kingdom	Automatic Micro-drill	Experimental	Stap

TMF tympanomeatal flap, *Scut* lowering of the scutum, *Crur* sectioning of tendon and crura, *Stap* stapedotomy, *Prost* prosthesis placement, *Crimp* crimping

*PORP and TORP prosthesis were placed for chronic ear infections

Conclusion

While the surgical steps of stapedotomy/stapedectomy have not changed, new tools are being developed to improve the safety and outcome of the procedure. Endoscopic ear surgery is increasingly applied and reaches to stapes surgery too. Reported outcome is similar to a microscopic approach, with an advantage of less postoperative dysgeusia and pain. Robotical assistance is under development for application in the clinical setting. Further studies in a prospective setting are needed to evaluate if a surgical technique is superior to the other.

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Compliance with Ethical Standards

Conflict of Interest LA is a consultant for Stryker ENT. The other authors declare that they have no conflict of interest.

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