AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

OTO Open
2021, Vol. 5(4) 1–10

DOI: 10.1177/2473974X211057035
http://oto-open.org
SAGE

New Medical Device and Therapeutic Approvals in Otolaryngology: State of the Art Review 2020

Michael J. Brenner, MD[1,2], Jared A. Shenson, MD[1,3], Austin S. Rose, MD, MBA[1,4], Tulio A. Valdez, MD, MSc[1,3], Masayoshi Takashima, MD[1,5], Omar G. Ahmed, MD[1,5], Philip A. Weissbrod, MD[1,6], Robert S. Hong, MD, PhD[1,7,8], Hamid Djalilian, MD[1,9], Jeffrey S. Wolf, MD[1,10], Robert J. Morrison, MD[1,2], Peter L. Santa Maria, MBBS, PhD[1,3], and Isaac D. Erbele, MD[1,11,12]

Abstract

Objectives. To evaluate new drugs and devices relevant to otolaryngology–head and neck surgery that were approved by the US Food and Drug Administration (FDA) in 2020.

Data Sources. Publicly available device and therapeutic approvals from ENT (ear, nose, and throat), anesthesia, neurology (neurosurgery), and plastic and general surgery FDA committees.

Review Methods. Members of the American Academy of Otolaryngology–Head and Neck Surgery's Medical Devices and Drugs Committee reviewed new therapeutics and medical devices from a query of the FDA's device and therapeutic approvals. Two independent reviewers assessed the drug's or device's relevance to otolaryngology, classified to subspecialty field, with a critical review of available scientific literature.

Conclusions. The Medical Devices and Drugs Committee reviewed 53 new therapeutics and 1094 devices (89 ENT, 140 anesthesia, 511 plastic and general surgery, and 354 neurology) approved in 2020. Ten drugs and 17 devices were considered relevant to the otolaryngology community. Rhinology saw significant improvements around image guidance systems; indications for cochlear implantation expanded; several new monoclonal therapeutics were added to head and neck oncology's armamentarium; and several new approvals appeared for facial plastics surgery, pediatric otolaryngology, and comprehensive otolaryngology.

Implications for Practice. New technologies and pharmaceuticals offer the promise of improving how we care for otolaryngology patients. However, judicious introduction of innovations into practice requires a nuanced understanding of safety, advantages, and limitations. Working knowledge of new drugs and medical devices approved for the market helps clinicians tailor patient care accordingly.

Keywords

medical device, therapeutic, drug, FDA

Received January 30, 2021; accepted October 11, 2021.

[1]Medical Devices and Drugs Committee, American Academy of Otolaryngology–Head and Neck Surgery, Alexandria, Virginia, USA
[2]Department of Otolaryngology–Head and Neck Surgery, University of Michigan Medical School, Ann Arbor, Michigan, USA
[3]Department of Otolaryngology–Head and Neck Surgery, Stanford University, Palo Alto, California, USA
[4]Department of Otolaryngology–Head and Neck Surgery, School of Medicine, University of North Carolina, Chapel Hill, North Carolina, USA
[5]Department of Otolaryngology–Head and Neck Surgery, Houston Methodist Hospital, Houston, Texas, USA
[6]Division of Otolaryngology, Department of Surgery, University of California San Diego, La Jolla, California, USA
[7]Department of Otolaryngology–Head and Neck Surgery, Wayne State University, Detroit, Michigan, USA
[8]Michigan Ear Institute, Farmington Hills, Michigan, USA
[9]Department of Otolaryngology–Head and Neck Surgery and Biomedical Engineering, University of California–Irvine, Irvine, California, USA
[10]Department of Otolaryngology–Head and Neck Surgery, School of Medicine, University of Maryland, Baltimore, Maryland, USA
[11]Department of Otolaryngology, Brooke Army Medical Center, Fort Sam Houston, Texas, USA
[12]Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, Maryland, USA

The views expressed herein are those of the authors and do not reflect the official policy or position of the Brooke Army Medical Center, the US Army Medical Department, the US Army Office of the Surgeon General, the Department of the Army, the Department of the Air Force, the Department of Defense, or the US government.

Corresponding Author:
Isaac D. Erbele, MD, Department of Otolaryngology, Brooke Army Medical Center, 3551 Roger Brooke Dr, Fort Sam Houston, TX 78234, USA.
Email: isaac.d.erbele.mil@mail.mil

Medical knowledge and technological innovations are expanding at an exponential rate.[1] Such progress allows surgeons to offer promising new therapies and improve on existing ones. However, as the rate of discovery and invention accelerates, it becomes increasingly difficult for busy clinicians to evaluate the evidence and judgments that are critical to deciding how and when to assimilate new innovations into practices. The Medical Devices and Drugs Committee of the American Academy of Otolaryngology–Head and Neck Surgery helps to address this need by reviewing US Food and Drug Administration (FDA) approvals on an annual basis.[2] The FDA has a charge to ensure that only safe and effective drugs and devices enter the market, serving as the gatekeeper for essential and novel therapies that otolaryngologists may bring to patients. This state of the art review critically evaluates drugs and devices approved in the 2020 calendar year.

Methods

Review of FDA approvals was conducted in accordance with procedures previously described by the American Academy of Otolaryngology–Head and Neck Surgery's Medical Devices and Drugs Committee.[2] Publicly available records from the FDA were queried for drug and device approvals or modifications from January 1 to December 31, 2020. For devices, approved 510(k) premarket submissions, premarket authorizations, and de novo products were reviewed.[3-5] FDA databases for ENT (ear, nose, and throat), anesthesia, neurosurgery, and plastic and general surgery were evaluated. Approved novel drugs were also reviewed.[6] Products were then prioritized by relevance, novelty, and impact to the specialty, as assessed by 2 independent reviewers, at least 1 of whom had fellowship training in the applicable subspecialty or commensurate expertise (**Figure 1**, **Table 1**). If needed, companies were contacted to clarify details and to secure permission to share images of their products.

All novel drugs and medical devices identified as relevant to otolaryngology were reviewed. Renewals of existing products, incremental product updates, and products not applicable to otolaryngology practice were excluded. A total of 53 novel drugs were approved by the FDA during the 2020 calendar year, of which 10 were relevant to otolaryngology. In addition, 1094 devices from relevant FDA committees were approved (89 ENT, 140 anesthesia, 511 plastic and general surgery, and 354 neurology), of which 17 were relevant to otolaryngology (**Table 2**). The scientific evidence supporting each device or therapeutic varied widely, ranging from case series reported exclusively to the FDA to several large peer-reviewed randomized controlled trials. Therapies relevant to the COVID-19 pandemic were excluded, as these products require a dedicated comprehensive review.

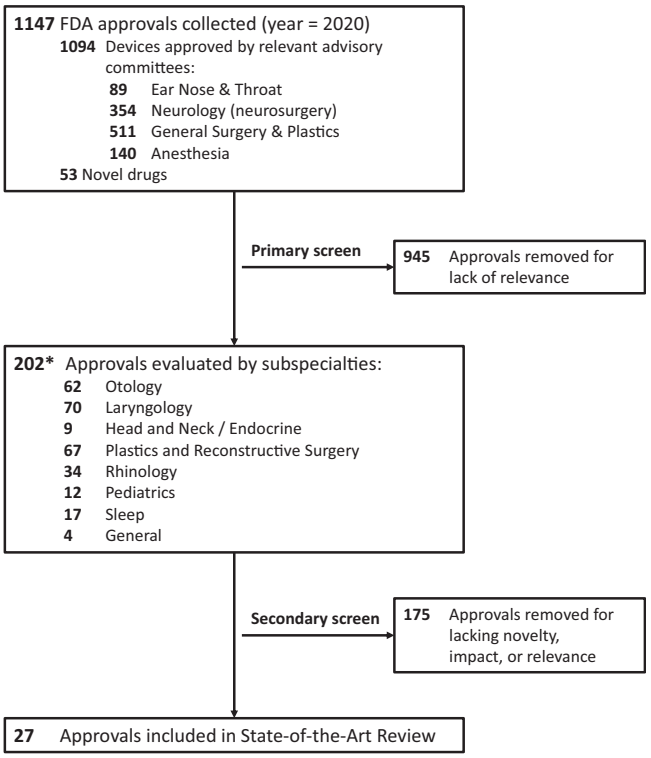

Figure 1. Data collection to state of the art review inclusion. FDA, Food and Drug Administration. Refer to **Table 1** for screening criteria.

Table 1. Criteria for Screening FDA-Approved Drugs and Devices.

Lack of relevance	Lack of novelty or impact
• A device or drug not applicable to the scope of typical practice in otolaryngology • An approval that does not address a defined need or improve care in otolaryngology	• Renewal of a previous FDA approval • Incremental change in an existing product or minor update to an existing approval (eg, for changes in supply chain) • Rebranding or introduction of a non–first-in-class that does not differentiate from a previously approved product (eg, new hyaluronic acid filler)

Abbreviation: FDA, Food and Drug Administration.

Discussion

Otology

Expanded Cochlear Implant Indications. The Nucleus 24 Cochlear Implant System (Cochlear Americas) was originally approved by the FDA in 1998 to restore auditory sensation to adults and children via electrical stimulation of the auditory nerve. In March 2020, the FDA approved expanded indications for this device to include infants between 9 and 12 months old with bilateral profound sensorineural hearing loss. Previously, it was approved only for patients $\geq$12 months old. The expanded approval relied on (1) a systematic review of 49 peer-reviewed articles of cochlear implantation from 750 patients $<$12 months in age

Table 2. Otolaryngology-Relevant Devices and Drugs Approved by the Food and Drug Administration in 2020 by Subspecialty.[a]

	Devices (n = 17)	Drugs (n = 10)
Otology	Nucleus 24 Cochlear Implant	None
	Orion Chair	
	TRV Chair	
	Colibri Endoscope	
Laryngology	None	berotralstat (Orladeyo)
Head and neck/endocrine	None	tazemostat (Tazverik)
		selumetinib (Koselugo)
		selpercatinib (Retevmo)
		pralsetinib (Gavreto)
		teprotumumab (Tepezza)
		tirbanibulin (Klisyri)
Plastics	Hemoblast Bellows	oxymetazoline (Upneeq)
	StarPore	
Rhinology	Novapak	None
	DrillCut-X	
	TruDi	
	TruDi Curette	
	Stryker ENT Navigation–Universal Headrest	
	TGS Guidewire	
	XprESS LoProfile ENT Dilation System	
	ClearPath Nasal Balloon Catheter	
Pediatrics	Hummingbird TTS	None
	Bizact	
Sleep	None	None
General	Otoset	rimegepant (Nurtec ODT)
		eptinezumab (Vyepti)

[a]Refer to the text for details about each product.

provided to the FDA and (2) an analysis of 84 pediatric subjects between 9 and 12 months old who received a Nucleus 24 cochlear implant from 1 of 5 cochlear implant centers across the United States and Canada.[7] The systemic review demonstrated comparable safety of cochlear implantation for patients younger and older than 12 months, and individuals implanted at <12 months of age received significant benefit in speech and language development. The 84-subject study demonstrated low adverse event rates: 2.4% cerebral spinal fluid leak, 2.4% temporary facial weakness, 2.4% infection, 7.1% minor postoperative complication, 3.6% minor skin irritation, 3.6% otitis media, 2.4% seroma, and 7.1% temperature dysregulation during the procedure. A majority of these adverse events, 26 of 28, resolved without major surgical or medical intervention. There were no reports of postoperative meningitis, device failures, device extrusions, or other serious device malfunctions.

Orion Chair for Vestibular Evaluation. The Orion Chair (Interacoustics) is a new rotatory chair for vestibular assessment. An attractive optional feature is the ability to recline the chair, allowing videonystagmography for other vestibular tests within the same device and space. The chair also allows off-axis rotational acceleration to be studied.[8] This product competes with the Neuro-Kinetics NOTC system,[9] which was the only similar device on the market for years.

TRV Chair for Benign Paroxysmal Positional Vertigo. The TRV Chair, also by Interacoustics, is designed for benign paroxysmal positional vertigo testing and rehabilitation. This chair effectively replaces the Epley Omniax Chair (Vesticon), whose business recently withdrew from the market. Unlike the Omniax Chair, the TRV Chair is manually operated, which eliminates the risk of motor failures seen in the Omniax.

The TRV Chair has been favorably compared to the Omniax.[10] In a recent study, Pedersen and colleagues diagnosed and treated 81 patients with refractory benign positional vertigo using the TVR Chair.[11] Successful treatment within this population was found in 92% of patients, requiring an average of 2.2 (SD, 1.7) treatments. Ultimately, these chairs do not improve the efficacy of the canalith repositioning maneuver, but they do allow repositioning maneuvers in patients who cannot easily lie down and turn the neck.

Colibri Endoscope System for Otologic Surgery. In the evolving field of endoscopic ear surgery, one challenge has been the

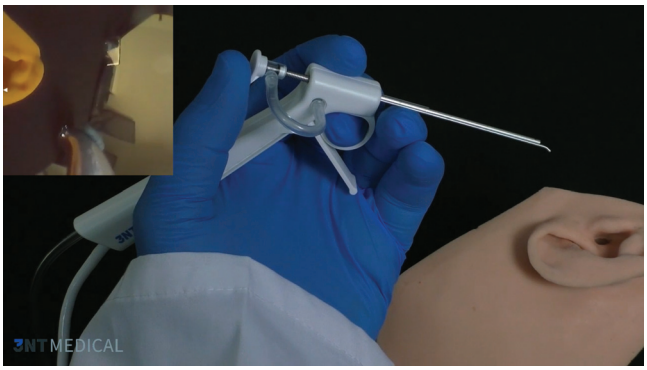

Figure 2. Colibri endoscope system for otologic surgery.

need to change between dissecting instruments and a suction with a single operative hand. The Colibri ear endoscope system (3NT Medical Ltd) places a suction through a working channel around a disposable endoscope (**Figure 2**), allowing the suction and endoscope to be combined. This suction can rotate, helping to approximate 2-handed surgery and thereby addressing one of the frequent criticisms of otoendoscopic surgery. The length is 64 mm, approximating other otologic instruments. The endoscope is at a 0° angle and is 2.2 mm in optical diameter. This reduces some image quality when compared with larger-diameter endoscopes, but some surgeons may find this a worthwhile trade since it reduces instrument exchanges.

The Colibri ear endoscope is one of many single-use endoscopes entering the market this year but the only one meriting committee review (the other 2 single-use endoscopes reviewed were principally of pulmonology interest and excluded). In the coming years, novel single-use endoscopes are anticipated across otolaryngology. Single-use products have appeal due to the elimination of infection risk from inadequate cleaning, avoidance of regulatory challenges with processing and storage, and obviating the need for costly scope repairs.[12,13] In one recent study, direct cost assessment between a disposable and reusable video laryngoscope system suggested a saving per use favoring single-use scopes.[14] However, cost is multifactorial and likely varies by the type of endoscope system, life span of the reusable system, and frequency and extent of repairs.

Laryngology

Berotralstat Hydrocholoride for Hereditary Angioedema. Berotralstat (Orladeyo; Biocryst Pharmaceuticals, Inc) is the first oral nonandrogen medication approved for use for hereditary angioedema (HAE). HAE is a rare disease caused by C1 esterase inhibitor deficiency, mediated by overproduction of bradykinin secondary to unregulated kallikrein activity.[15] Bradykinin production leads to vasodilation and vascular permeability and leakage, as well as subsequent swelling of the lips, tongue, and larynx that may precipitate airway emergencies.[16] Berotralstat is a once-daily oral selective kallikrein inhibitor for long-term prophylactic treatment of HAE that has been shown to significantly reduce the frequency of angioedema attacks as compared with placebo.[17] Adverse events are mild, and most typically consist of abdominal pain, nausea, vomiting, diarrhea, and back pain. As a therapeutic, its advantages over existing treatments include oral dosing and requiring no special preparation or storage.

Head and Neck/Endocrine

Tazemetostat for Epithelioid Sarcoma. Epithelioid sarcoma is a rare, locally aggressive soft tissue malignancy that typically arises in the extremities of young adults but rarely occurs in the head and neck.[18-20] Current treatment paradigms usually involve surgery with adjuvant chemotherapy ± radiation therapy. Tazemostat (Tazverik; Epizyme) is an inhibitor of the methyltransferase EZH2, which has aberrantly upregulated activity in most epithelioid sarcomas. In a phase II open-label study of patients with advanced disease that is unresectable, recurrent, or metastatic, tazemostat provided a modest benefit with a 15% objective response rate (all partial response) and a 26% disease control rate (stable or decreasing extent of disease for >32 weeks).[21] Tazemostat is a molecular-targeted therapeutic option for patients with disease refractory to standard treatment and should be considered only within multidisciplinary discussions, ideally at specialized oncology centers with expertise in soft tissue sarcomas.

Selumetinib for Plexiform Neurofibromas in Neurofibromatosis Type 1. Plexiform neurofibromas are pathognomonic of neurofibromatosis type 1 (NF1), occurring in approximately 30% of patients.[22] Plexiform neurofibromas commonly affect cranial nerves and brachial plexus. They may infiltrate into the surrounding soft tissues, resulting in unresectable lesions or high rates of recurrence when resectable.[22] Although usually benign, there is a 5%-10% lifetime risk of malignant transformation, correlating with lesion size. Selumetinib (Koselugo; AstraZeneca) is an oral MEK1/2 inhibitor, which blocks the activity of the RAS-regulated RAF-MEK-ERK pathway. This pathway has been implicated in neurofibroma pathogenesis in NF1 and is activated in several other tumors, including some thyroid carcinomas.[23,24] The SPRINT phase II open-label study of selumetinib in patients with unresectable plexiform neurofibromas demonstrated a 66% objective response rate, defined as at least a 20% tumor volume decrease. The response was durable (82% with response lasting >1 year).[25] Treatment was generally well tolerated, with primary side effects of gastrointestinal upset and rash. Selumetinib is recommended for primary treatment of unresectable plexiform neurofibromas.

Selpercatinib and Pralsetinib for Thyroid Cancer With RET *Gene Mutation.* Among some thyroid cancers, *RET* mutations or protein fusions drive tumorigenesis through constitutive activation of the MAPK pathway. *RET* mutations/fusions are found in 5% to 30% of cases of papillary thyroid carcinoma; in nearly all cases (96%) of familial medullary thyroid carcinoma (MTC), including patients with multiple

endocrine neoplasia syndrome types 2A and 2B; and in about 50% of cases of sporadic MTC.[26] MTC is often aggressive, with a high propensity for regional and distant metastatic spread.[27] In patients with locally advanced disease or significant burden of distant metastases, external beam radiation therapy and systemic therapy are considered.[27] Systemic therapy options have been limited, as MTC is not sensitive to radioactive iodine and nonselective multikinase inhibitors have had disappointingly low long-term efficacy due to acquired resistance mutations.[26] Selpercatinib (Retevmo; Loxo Oncology) and pralsetinib (Gavreto; Blueprint Medicines) are novel oral *RET* kinase inhibitors approved for treatment of *RET*-mutated locally advanced and metastatic thyroid carcinoma. The phase I/II LIBRETTO-001[28] and ARROW[29] trials, respectively, demonstrated 62–91% objective response rate with durable response and low side effect profile. Use of a *RET*-specific inhibitor is now recommended instead of MKIs in advanced *RET*-driven thyroid carcinomas. Additional clinical trials will help to define whether *RET*-specific inhibitors may provide benefit in the neoadjuvant setting to reduce the morbidity of surgical treatment for locally advanced disease and/or treat metastatic disease concurrently with locoregional surgery.[30] Low-volume locoregional disease will likely remain primarily treated by surgery, with systemic therapy reserved for locally advanced, recurrent, or metastatic disease.

Teprotumumab for Thyroid Eye Disease. Thyroid eye disease (thyroid ophthalmopathy) affects up to 40% of patients with autoimmune thyroiditis and does not consistently resolve with correction of thyroid dysfunction. Patients may have progressive proptosis and eventual optic nerve compression requiring orbital decompression. Insulin-like growth factor type 1 receptors (IGF-1Rs) have been implicated in thyroid eye disease, and teprotumumab (Tepezza; Horizon Therapeutics, PLC) is a human monoclonal antibody directed against IGF-1R. It is given intravenously once every 3 weeks for 8 doses. In a randomized controlled trial in 83 patients with active thyroid eye disease, 83% in the treatment arm had reduction in proptosis. Common side effects included muscle spasm and alopecia.[31] After FDA approval, there was a single case report of rapidly progressive cognitive decline occurring after the third dose, suggesting a teprotumumab-induced encephalopathy.[32] This finding may prompt caution in prescribing by endocrinologists and ophthalmologists. Teprotumumab is used primarily treat active disease, and chronic thyroid eye disease will likely continue to be treated with surgical decompression.

Tirbanibulin for Actinic Keratosis. Tirbanibulin (Klisyri; Almirall) is a 1% topical ointment indicated for treatment of actinic keratosis (AK) of the face and scalp.[33] AK can present a cosmetic challenge when involving large areas of the face that make surgical excision challenging. Tirbanibulin selectively inhibits cellular tubulin polymerization, interfering with the proliferation of atypical keratinocytes. Reversible binding of tirbanibulin to the colchicine-binding site of β-tubulin explains low clinical toxicity.[34] Double-blind, vehicle-controlled randomized multicenter trials, enrolling 702 patients in 62 sites in the United States (87% men, 13% women, 99% White, 73% aged ≥65 years), established the efficacy of topical application of tirbanibulin to a single predetermined 25 cm^2 on the face or scalp with 4 to 8 AKs (once daily for 5 days). Among treated patients, 44% to 54% had complete clearance at day 57 on the face or scalp treatment areas. The most common side effects included application site pruritus or pain.[35,36] Up to 65% of cutaneous squamous cell carcinoma cases originate from AKs; tirbanibulin adds to the armamentarium of therapies to prevent AK progression to squamous cell carcinoma.

Plastic and Reconstructive Surgery

Oxymetazoline for Blepharoptosis. Routinely used for nasal mucosal vasoconstriction and decongestion, oxymetazoline recently became the first FDA-approved pharmacologic treatment for acquired blepharoptosis. Marketed as Upneeq (oxymetazoline hydrochloride ophthalmic solution 0.1%; RVL Pharmaceuticals, Inc), the topical drops are indicated for acquired ptosis, which often results from impairment of the Müller's muscle that elevates the eyelid in conjunction with the levator superioris. In clinical trials of 360 subjects with acquired ptosis (203 treated for 6 weeks, 157 treated for 12 weeks), oxymetazoline significantly improved superior visual fields vs placebo, as measured by the Leicester Peripheral Field Test on hour 6, day 1, with a value of 6.3 for oxymetazoline vs 2.1 for vehicle ($P < .0001$) and with similar efficacy on hour 2, day 14, at 7.7 for oxymetazoline vs 2.4 for vehicle ($P < .0001$). It also improved outcomes on the Marginal Reflex Distance Test, which measures the distance from the center of the pupillary light reflex to the upper eyelid margin. Oxymetazoline was well tolerated over 6- and 12-week periods in safety trials; adverse reactions occurred in 1% to 5% of subjects, including punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation, and headache.[37]

Hemoblast for Hemostasis. The Hemoblast Bellows (Biom'Up) is a handheld hemostasis device, where the surgeon squeezes the bellows to release sterile porcine collagen powder with glucose, chondroitin sulfate, and thrombin to achieve hemostasis during surgical procedures. The collagen powder absorbs ambient blood to facilitate coagulation; thrombin facilitates conversion of fibrinogen to fibrin; and chondroitin sulfate powder provides cohesion between the hemostatic wound and the surrounding tissue. The hemostatic agent combines tamponade and acceleration of fibrin clot formation as an adjunct to hemostasis when conventional procedures are impractical. To avoid risk of allergic-anaphylactic reaction and/or thromboembolic events, the product should not be introduced directly into vessels. A randomized study in 242 patients across 16 sites evaluated the safety and efficacy of Hemoblast Bellows against absorbable gelatin sponge and thrombin. The data showed enhanced coagulation with the device, including 71.1% vs 45.8% cessation of bleeding at 3 minutes ($P = .001$) and 93.1% vs 73.5% at 6 minutes ($P =$

.001). There were no clinical signs or symptoms of postoperative bleeding with Hemoblast Bellows.[38] This product has found use in cardiac and abdominal surgery; it may find use in large head and neck procedures.

StarPore for Aesthetic Rigid Implantation. StarPore implants (Anatomics, Pty, Ltd) include a series of anatomically contoured high-density polyethylene surgical implants designed for cartilage or bony reconstruction.[39] They are made of star-shaped particles that form an interconnecting porous architecture analogous to the stellate character of trabecular bone, allowing for rapid infiltration of vascular tissue that may facilitate implant anchoring to tissues adjacent to the implant. The StarPore implant is strong and malleable, not susceptible to cracking or fracturing, and can be fixated with screws. Patient-specific implants based on available imaging are available. Any permanent implant is susceptible to complications of infection, extrusion, displacement, or adjacent bony resorption. Similar, precedent devices are generally well tolerated.

Rhinology

Novapak for Nasal Hemostasis. Novapak (Medtronic Xomed, PLC) was approved as a nasal packing and stent for use following sinus surgery or in the treatment of epistaxis. It is made of formulated chitosan and cellulose. The product prevents adhesions, controls mild bleeding, and may have antibacterial properties. The material, which can be cut to size and compressed for insertion, hydrates with sterile saline forming a gel. The sponge dissolves within the nasal cavity over 7 to 14 days with daily irrigation and natural mucus flow. Alternately, the dressing may be removed through gentle aspiration during postoperative debridement. Novapak is similar to NasoPore (fragmentable poly [DL-Lactide-co-e-caprolactone] urethane; Stryker ENT), but Novapak, according to studies supplied with its regulatory submission, has the potential additional benefit of providing a protective barrier to deter bacterial growth for up to 72 hours. In a meta-analysis published in 2017, Zhou et al found that, when compared with controls, a chitosan dressing similar to the material used in Novapak could significantly decrease edema and improve hemostasis, but it had no effect on granulations, mucosal edema, crusting, and infection.[40] Novapak contains chitosan from shellfish and is contraindicated in patients with known shellfish allergies.

DrilCut-X for Endonasal Drilling. Karl Storz Endoscopy-America, Inc received clearance for the DrillCut-X II-35 Handpiece With 35k Sinus Burrs. This newly designed handpiece works with the Unidrive S III motor control unit, and various drill burr and sinus attachments are available. An optional handle is available to improve control and ergonomic feel (**Figure 3**). The device incorporates suction and irrigation capabilities and can be adapted for use with various existing image-guided surgical systems from Karl Storz. The device is optimized for drilling and shaver functions in the sinonasal area at high speed—up to 35,000 rotations per minute (RPM) for drill burrs and 10,000 RPM for shaver blades. A significant increase from prior drills and shavers commonly used in rhinology, this level of RPM offers the potential for improved control, precision, and safety.

Figure 3. DrillCut-X II-35 Handpiece With 35k Sinus Burrs for sinus surgery.

High-speed drilling has become recognized as a high-risk aerosol-generating procedure in the COVID-19 era. Recent work suggests that the presence of incorporated suction during drilling, in contrast to traditional drills, may reduce detectable droplet contamination outside the nasal cavity.[41] This device reflects progressive innovation over decades with significant improvements in drilling and shaving capabilities. Such instrumentation is now indispensable in the safe and effective surgical treatment of chronic sinusitis and other sinonasal pathologies.

Updates to the TruDi System for Image-Guided Surgery. TruDi is the newest image-guided surgery (IGS) system by Johnson & Johnson Medical Devices (Acclarent) and updates its previous electromagnetic (EM) navigation system. The system can now import magnetic resonance scans and has a new TruMerge feature, allowing automatic merging of computed tomography and magnetic resonance scans. This is particularly helpful for endoscopic skull base surgery. The new version can connect to the facility's PACS server (picture archiving and communication system) and can easily load scans directly from the network via TruPACS.

There is a new single-use TruDi probe that is compatible with the new TruDi navigation system, allowing intraoperative tracking. There are 2 probe configurations: straight (0°) and frontal (70°). Each probe comes with a disposable bending tool to adjust the configuration of the malleable tip. The advantages of this new tool include the ergonomic handle, low-profile design that improves maneuverability in tight anatomy, and malleable tip. A new malleable TruDi Curette is available and compatible with the system. This curette has an advantage over traditional sinus curettes because its distal tip sensor can be tracked during IGS. It comes with a disposable bending tool, which allows the surgeon to customize the shape of the distal shaft. It can bend anywhere from 0° to 90° to dissect and remove bone from the sinuses and skull

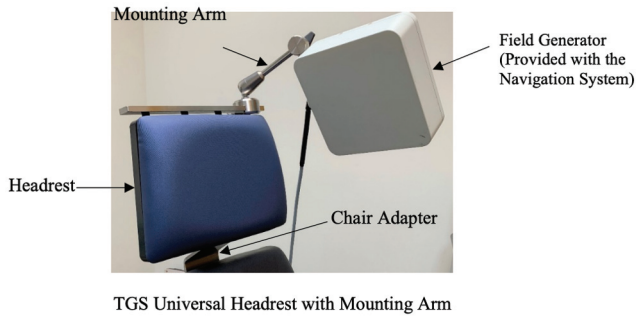

Figure 4. Stryker ENT TGS Universal Headrest With Mounting Arm for in-office image guided navigation.

base. It has gripping features on the shaft that assist with tactile feel.

Updates to the Stryker ENT Navigation System for IGS. The rapid increase in office-based sinus procedures over the past decade has created a demand for office-based navigation systems. Most manufacturers of operating room–based EM navigation systems offer versions that may be used in clinic. The Stryker ENT Navigation System offers a new universal headrest with mounting arm for its TGS image guidance (**Figure 4**). This reusable device contains a headrest and chair adapter compatible with most ENT office chairs and a mounting arm that attaches to the headrest. The mounting arm provides fixation for the field generator of the navigation system and allows it to be positioned proximal to the patient's head. This modification to its traditional field generator mounting arm provides convenience for consistent placement.

Stryker ENT has also developed the TGS Guidewire, which provides image guidance for the EM Navigation System and the XprESS LoProfile ENT Dilation System. The catheter is easily threaded through the balloon dilation system, aids localization of anatomic structures, and may prevent cerebrospinal fluid leak or scarring from incorrect placement. This device is similar to the TruDi Navwire (Johnson & Johnson Medical Devices), which was FDA approved in 2019. The main difference between the 2 EM guidewires are the intended balloon dilation systems and compatibility with navigation systems. Guidewires and IGS for balloon sinuplasty for frontal and sphenoid sinuses may become standard of care, mimicking traditional endoscopic sinus surgery.

ClearPath Nasal Balloon Catheter for Inferior Turbinate Displacement. The ClearPath Nasal Balloon Catheter (Intuit Medical Products) is a single-use balloon catheter that displaces the inferior turbinate and lower nasal septum to increase intranasal space. This product competes with the Relieva Tract Nasal Dilation System (Johnson & Johnson Medical Devices), offering a shorter length (25 vs 40 cm). The working end of the ClearPath device has a guide ''spatula'' on one side and the balloon on the other (**Figure 5**). This allows the surgeon to selectively address nasal anatomy. The balloon applies force to the structure intended to be mobilized (eg, inferior turbinate), while distributing the opposing force to a larger area and protecting it from injury. Future studies on nasal septal balloon systems are needed to evaluate long-term outcomes on intranasal space and clinical relief of nasal obstruction.

Pediatrics

Expanded Indications for Hummingbird TTS (Tympanostomy Tube System) for In-Office Tympanostomy Tube Placement. The Hummingbird tympanostomy tube system (Preceptis Medical) is an in-office tympanostomy tube placement device for children 6 to 24 months of age. It was previously approved for use in conscious sedation, and it is now approved for awake, restrained patients. The expanded indications allow it to continue to compete with the Tula System (Tusker Medical), which was approved for similar indications last year.[2] The Hummingbird device combines the separate steps of making a myringotomy, positioning the pressure equalization tube, and placing the tube with alligator forceps or picks. It has a 1-pass system: an incision is made with the cutting sheath, and the tube is placed by scrolling back on the slider. Insertion requires topical anesthetic. According to the FDA application data, tube insertion was completed with a median time of 5 minutes, and 99% of children successfully received ear tubes in the office; 85% of the time, it was successful with the first pass.[42]

Expanded Indications for BiZact Tonsillectomy Device. The BiZact (Covidien, LLC) is a tonsillectomy device that has an ergonomic handle, a 12-cm shaft, and a curved jaw with bipolar electrocautery. It was previously approved for patients $\geq$12 years old, and it now has an indication for patients $\geq$3 years old.[43] The ergonomic design allows use with both hands and is designed to follow the shape of the tonsil bed. The curved jaw allows for dissection and sealing while dividing tissue, possibly improving operative time. In a study by Krishnan et al, the average surgical time with the device was 5.1 minutes for all age groups, and the postoperative bleed rate was 4.3%.[44]

General

Otoset Ear Cleaning System for Ear Wax Removal. Otoset (Safkan Health) is the first automated FDA-approved ear cleaning device for clinical use.[45] It is approved for adults. It combines liquid flow and a microsuction to break down and remove impacted cerumen. The Otoset system includes a headphone-like apparatus with a fluid reservoir, suction, and disposable ear tips (**Figure 6**). The device uses a 35-second cleaning cycle where liquid flow is directed from solution containers through disposable ear tips and toward the walls of the ear canals to break down cerumen. Continuous microsuction draws the earwax and liquid back through the ear tips and into disposable waste containers to limit water spills during the earwax removal procedure. Primary care clinics, where a microscope for cerumen

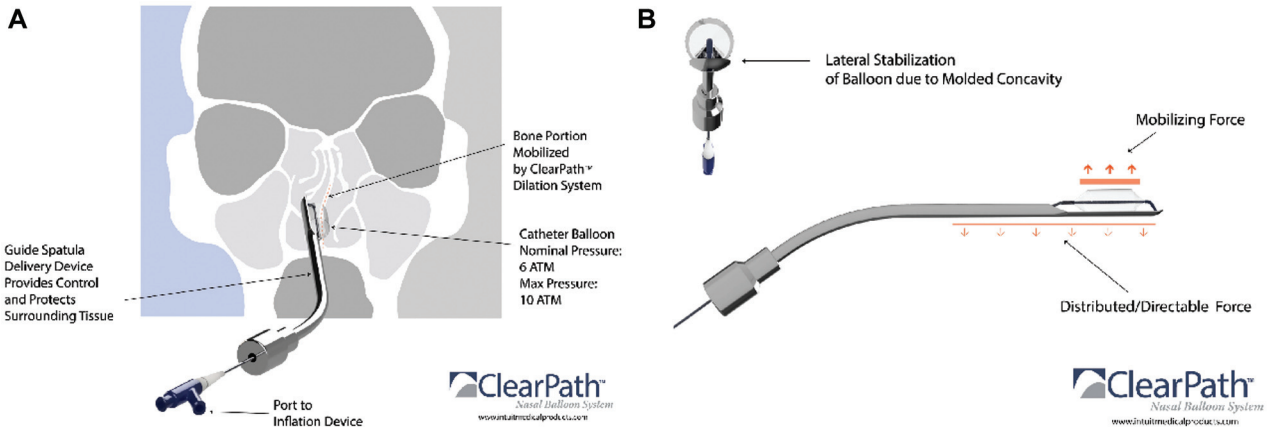

Figure 5. ClearPath nasal dilation system. The working end has a balloon on one side and a spatula on the other, preventing injury to the side away from the balloon.

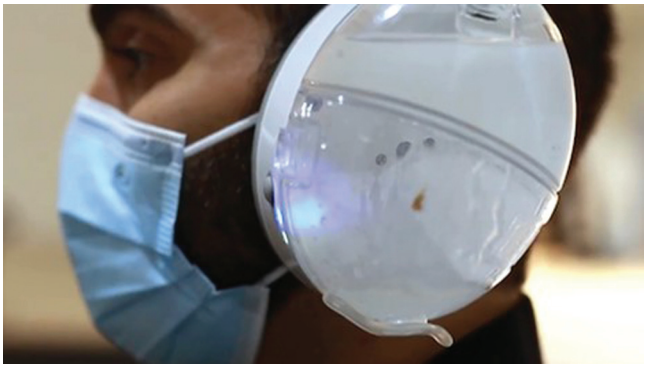

Figure 6. Otoset cerumen removal device.

removal may not be readily available, are likely the target market.

Rimegepant and Eptinezumab for Migraine. Although most otolaryngologists do not routinely treat migraine, they have a role in managing or referring vestibular migraine, atypical facial pain, and other migrainous disabilities. Treatment for migraine is evolving rapidly, and 2 medical therapies were newly approved. Notably, these therapeutics are promising for migraine headache, but there is a paucity of data on treatment of atypical facial pain or vestibular migraine.

Rimegepant (Nurtec ODT; Biohaven Pharmaceuticals, Inc) is a calcitonin gene-related peptide receptor agonist approved for the treatment of acute migraine, dosed as an oral dissolvable tablet. In a double-blind randomized controlled trial by Croop et al, migraine was resolved in 21% of patients as opposed to 11% in placebo at 2 hours after therapy.[46] Although approved for acute migraine, recent work suggests that it may be effective for migraine prevention; this is a unique finding for migraine therapies.[47] Adverse reactions are typically nausea and nasopharyngitis, which occur at nearly the same rate as placebo.

Eptinezumab (Vyepti; Lundbeck Seattle BioPharmaceuticals, Inc) was approved for migraine prevention. It targets the calcitonin gene-related peptide receptor, though with an anticlonal antibody requiring intravenous administration. In a randomized controlled trial by Lipton and colleagues, patients experienced about 2 fewer migraine episodes a month than placebo. Nasopharyngitis, fatigue, and nausea were slightly more common than placebo.[48]

Limitations

The FDA is a conservative body, and the drugs and devices approved may be years behind the innovations reported in the academic literature or the technologies available to the market outside the United States. However, some approved technologies have limited scientific data available to assess their role in practice or long-term outcomes. This limitation is acutely evident with teprotumumab for thyroid eye disease, where a case of cognitive decline was identified only in postmarket surveillance.[32] Furthermore, there is subjectivity inherent in determining which drugs and devices were clinically relevant to the specialty, and discussion of incremental advances was limited by prioritization. Finally, despite our effort to be exhaustive, otolaryngology is a very broad field, and some impactful technologies may have been identified outside our queries.

Implications for Practice

Innovations available to the otolaryngologist change rapidly. Novel technologies have variable impact on care, with some new products losing relevance with time while others become paradigm shifting and establish new standards of care. Staying at the forefront of medical advances benefits our patients to ensure that they receive the highest-quality, safest care available.

Author Contributions

Michael J. Brenner, contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Jared A. Shenson,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Austin S. Rose,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be

accountable for its veracity; **Tulio A. Valdez,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Masayoshi Takashima,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Omar G. Ahmed,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Philip A. Weissbrod,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Robert S. Hong,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Hamid Djalilian,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Jeffrey S. Wolf,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Robert J. Morrison,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Peter L. Santa Maria,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity; **Isaac D. Erbele,** contributed to the study design, data acquisition, and analysis; approved the final manuscript; and agrees to be accountable for its veracity

Disclosures

Competing interests: Peter L. Santa Maria: Auration Biotech, Flotherm, Stryker. Robert S. Hong: Olympus. Hamid Djalilian: Beyond Tinnitus, Cactus Medical, Elinava Technologies. Austin S. Rose: Tivic Health Systems. Some FDA approvals were awarded to manufacturers that provide financial support to this journal's sponsoring society, the American Academy of Otolaryngology–Head and Neck Surgery Foundation. A listing of foundation donors is available at https://www.entnet.org/about-us/aao-hns-foundation/our-donors/.

Sponsorships: None.
Funding source: None.

ORCID iDs

Michael J. Brenner https://orcid.org/0000-0003-4926-0957
Jared A. Shenson https://orcid.org/0000-0001-7751-7508
Austin S. Rose https://orcid.org/0000-0003-3753-2329
Tulio A. Valdez https://orcid.org/0000-0002-8520-7910
Masayoshi Takashima https://orcid.org/0000-0001-9790-3529
Philip A. Weissbrod https://orcid.org/0000-0001-7977-6925
Hamid Djalilian https://orcid.org/0000-0001-5905-0270
Jeffrey S. Wolf https://orcid.org/0000-0003-3216-9620
Robert J. Morrison https://orcid.org/0000-0002-2313-8542
Peter L. Santa Maria https://orcid.org/0000-0002-3428-3497

References

1. Densen P. Challenges and opportunities facing medical education. *Trans Am Clin Climatol Assoc*. 2011;122:48-58.
2. Rameau A, Hong RS, Djalilian H, et al. New medical device and therapeutic approvals in otolaryngology: state of the art review of 2019. *OTO Open*. 2020;4(2):2473974x20932506.
3. US Food and Drug Administration. Device classification under section 513(f)(2)(de novo). Published 2020. Accessed February 8, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
4. US Food and Drug Administration. Premarket approval (PMA). Published 2020. Accessed February 8, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
5. US Food and Drug Administration. 510(k) premarket notification. Published 2020. Accessed February 8, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
6. US Food and Drug Administration. Novel drug approvals for 2020. Published 2020. Accessed February 8, 2021. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020
7. US Food and Drug Administration. Premarket approval (PMA): Nucleus 24 Cochlear Implant System. Published 2020. Accessed 6 May 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S172
8. Sugita-Kitajima A, Koizuka I. Evaluation of the vestibulo-ocular reflex using sinusoidal off-vertical axis rotation in patients with canal paresis. *Auris Nasus Larynx*. 2014;41(1):22-26.
9. Zalewski CK, McCaslin DL, Carlson ML. Rotary chair testing. In: Babu S, Schutt CA, Bojrab DI, eds. *Diagnosis and Treatment of Vestibular Disorders*. Springer International Publishing; 2019:75-98.
10. West N, Hansen S, Møller MN, Bloch SL, Klokker M. Repositioning chairs in benign paroxysmal positional vertigo: implications and clinical outcome. *Eur Arch Otorhinolaryngol*. 2016;273(3):573-580.
11. Pedersen MF, Eriksen HH, Kjaersgaard JB, Abrahamsen ER, Hougaard DD. Treatment of benign paroxysmal positional vertigo with the TRV reposition chair. *J Int Adv Otol*. 2020;16(2):176-182.
12. Kovaleva J, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev*. 2013;26(2):231-254.
13. Zhang Y, Zhou H, Jiang Q, Wang Q, Li S, Huang Y. Bronchoscope-related Pseudomonas aeruginosa pseudo-outbreak attributed to contaminated rinse water. *Am J Infect Control*. 2020;48(1):26-32.
14. Walczak R, Arnold M, Grewal J, Yuan X, Suryadevara A, Marzouk H. Reusable vs disposable nasopharyngolaryngoscopes: cost analysis and resident survey. *Laryngoscope Investig Otolaryngol*. 2021;6(1):88-93.
15. Zuraw BL, Christiansen SC. HAE pathophysiology and underlying mechanisms. *Clin Rev Allergy Immunol*. 2016;51(2):216-229.
16. Bork K, Meng G, Staubach P, Hardt J. Hereditary angioedema: new findings concerning symptoms, affected organs, and course. *Am J Med*. 2006;119(3):267-274.
17. Zuraw B, Lumry WR, Johnston DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: a randomized, double-blind, placebo-controlled phase 3 trial. *J Allergy Clin Immunol*. Published online October 21, 2020. doi: 10.1016/j.jaci.2020.10.015
18. Kim YS, Kwak HS, Chung GH, Kim YN, Hwang S. Epithelioid sarcoma arising from the temporal space: a case report. *Medicine (Baltimore)*. 2018;97(38):e12529.
19. Ueda Y, Chijiwa H, Nakashima T. Epithelioid sarcoma of the neck: case report. *J Laryngol Otol Suppl*. 2009(31):113-116.

20. Jurdy LL, Blank LE, Bras J, Saeed P. Orbital epithelioid sarcoma: a case report. *Ophthalmic Plast Reconstr Surg*. 2016; 32(2):e47-e48.
21. Stacchiotti S, Schoffski P, Jones R, et al. Safety and efficacy of tazemetostat, a first-in-class EZH2 inhibitor, in patients (pts) with epithelioid sarcoma (ES) (NCT02601950). *J Clin Oncol*. 2019;37(15, suppl):11003-11003.
22. Prada CE, Rangwala FA, Martin LJ, et al. Pediatric plexiform neurofibromas: impact on morbidity and mortality in neurofibromatosis type 1. *J Pediatr*. 2012;160(3):461-467.
23. Gross AM, Dombi E, Widemann BC. Current status of MEK inhibitors in the treatment of plexiform neurofibromas. *Childs Nerv Syst*. 2020;36(10):2443-2452.
24. Gross AM, Frone M, Gripp KW, et al. Advancing RAS/RASopathy therapies: an NCI-sponsored intramural and extramural collaboration for the study of RASopathies. *Am J Med Genet A*. 2020;182(4):866-876.
25. Gross AM, Wolters PL, Dombi E, et al. Selumetinib in children with inoperable plexiform neurofibromas. *N Engl J Med*. 2020; 382(15):1430-1442.
26. Porter A, Wong DJ. Perspectives on the treatment of advanced thyroid cancer: approved therapies, resistance mechanisms, and future directions. *Front Oncol*. 2020;10:592202.
27. Wells SA Jr, Asa SL, Dralle H, et al. Revised American Thyroid Association guidelines for the management of medullary thyroid carcinoma. *Thyroid*. 2015;25(6):567-610.
28. Wirth LJ, Sherman E, Robinson B, et al. Efficacy of selpercatinib in RET-altered thyroid cancers. *N Engl J Med*. 2020;383(9): 825-835.
29. Hu M, Subbiah V, Wirth L, et al. 1913O Results from the registrational phase I/II ARROW trial of pralsetinib (BLU-667) in patients (pts) with advanced RET mutation-positive medullary thyroid cancer (RET+ MTC). *Ann Oncol*. 2020;31:S1084.
30. Salvatore D, Santoro M, Schlumberger M. The importance of the RET gene in thyroid cancer and therapeutic implications. *Nat Rev Endocrinol*. 2021;17(5):296-306.
31. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the treatment of active thyroid eye disease. *N Engl J Med*. 2020; 382(4):341-352.
32. Hoang TD, Nguyen NT, Chou E, Shakir MK. Rapidly progressive cognitive decline associated with teprotumumab in thyroid eye disease. *BMJ Case Rep*. 2021;14(5):e242153.
33. US Food and Drug Administration. *Drug Approval Package: KLISYRI*. US Food and Drug Administration; 2020.
34. Niu L, Yang J, Yan W, et al. Reversible binding of the anticancer drug KXO1 (tirbanibulin) to the colchicine-binding site of beta-tubulin explains KXO1's low clinical toxicity. *J Biol Chem*. 2019;294(48):18099-18108.
35. US Food and Drug Administration. Drug trials snapshot: KLISYRI. Published 2021. Accessed April 12, 2021. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshot-klisyri
36. US National Library of Medicine. KLISYRI: tirbanibulin ointment. Published 2021. Accessed April 12, 2021. https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=589c8de8-b773-4d47-b60c-48471806cccc
37. US Food and Drug Administration. UPNEEQ (oxymetazoline hydrochloride ophthalmic solution), 0.1% for topical ophthalmic use. Published 2020. Accessed April 12, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/0212520s000lbl.pdf
38. US Food and Drug Administration. Premarket approval (PMA): Hemoblast Bellows. Published 2020. Accessed April 12, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P170012S023
39. US Food and Drug Administration. StarPore (Polymer, Ent Synthetic, Porous Polyethylene): 510(k) premarket Notification. Published 2020. Accessed April 12, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K200532
40. Zhou JC, Zhang JJ, Zhang W, Ke ZY, Zhang B. Efficacy of chitosan dressing on endoscopic sinus surgery: a systematic review and meta-analysis. *Eur Arch Otorhinolaryngol*. 2017;274(9): 3269-3274.
41. Leong SC, Mogre D, Andrews P, Davies E. Reducing the risks of endoscopic sinonasal surgery in the COVID-19 era. *Clin Otolaryngol*. Published online March 10, 2021. doi:10.1111/coa.13743
42. US Food and Drug Administration. Hummingbird tympanostomy tube system. Published 2020. Accessed May 24, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200952.pdf
43. US Food and Drug Administration. BiZact tonsillectomy device advanced bipolar tissue sealer/divider. Published 2020. Accessed May 24, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193356.pdf
44. Krishnan G, Stepan L, Du C, et al. Tonsillectomy using the BiZact: a pilot study in 186 children and adults. *Clin Otolaryngol*. 2019;44(3):392-396.
45. US Food and Drug Administration. OtoSet—Ear Cleaning System. Published 2020. Accessed May 24, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201877.pdf
46. Croop R, Goadsby PJ, Stock DA, et al. Efficacy, safety, and tolerability of rimegepant orally disintegrating tablet for the acute treatment of migraine: a randomised, phase 3, double-blind, placebo-controlled trial. *Lancet*. 2019;394(10200):737-745.
47. Croop R, Lipton RB, Kudrow D, et al. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. *Lancet*. 2021;397(10268):51-60.
48. Lipton RB, Goadsby PJ, Smith J, et al. Efficacy and safety of eptinezumab in patients with chronic migraine. *Neurology*. 2020;94(13):e1365-e1377.