Discussions About Gizmos

Richard Rosenfeld and Peter J. Koltai

Gizmos

Richard Rosenfeld

One attraction of the surgical specialties to medical students is the plethora of high-technology gizmos available to treat and diagnose disease. As the following discussion makes clear, distinguishing fanciful gizmos from truly useful technology is often no easy task.

Letter to the Editor

I would like to suggest a modern corollary to Benjamin Franklin's cautionary advice that "He's the best physician that knows the worthlessness of the most medicines."[1] In my opinion the best physician also knows the worthlessness of the most gizmos.

As a physician entering my fifth decade of practice I have witnessed countless colleagues succumb to the siren song of latest and greatest technology, also known as "gizmos." What better way to infuse excitement into a boring and mundane ailment than by bringing exotic, and often expensive, new devices, procedures, or techniques to the treatment paradigm?

Indeed, the more specialized a doctor becomes, the more appealing they seem to find unproven technology. Leff and Finucane[2] articulate the problem: "In the medical marketplace, some combination of avarice, hucksterism, credulity, genuine need, and *gizmo idolatry* impart considerable momentum to the early and unconsidered use of many unproved technologies. . . . Recognition of gizmo idolatry is a critical first step in educating consumers, both clinicians and patients, to be circumspect, rather than enthusiastic, and to seek evidence about the effectiveness of any medical technology."

Since otolaryngology is a medical discipline replete with gadgets and gizmos, many of which are discussed in articles published in your journal, I was hoping you could devote some time to this topic in an editorial. It's time to expose gizmo idolatry for what it really is.

Traditionally yours,

Lana Low-Tech, MD
Good Old Fashioned Gorge, USA

Editor's Response

"Correct me if I'm wrong," replied the Pulitzer Prize winning cartoonist Patrick ("Pat") Oliphant, "the gizmo is connected to the flingflang connected to the watzis, watzis connected to the doo-dad connected to the ding dong."[3] Perhaps this retort was preceded by a highfalutin sales pitch from a clinician enthralled with the latest gizmo acquired at a medical conference.

Whatever you call them—gizmos, gadgets, or even toys— they are deeply ingrained in the fabric of modern society.

Consumers enticed by the latest gizmos spend hours—or even days—perusing product reviews by experts and fellow consumers before committing to a purchase. But what degree of due diligence should be brought to bear before embracing the latest therapeutic medical gizmos, including robots, lasers, and balloons?

A Little History

History is replete with examples of mechanical devices used by clinicians, despite unproven efficacy, because of implicit convictions that more technology is intrinsically best.[2] Elisha Perkins, for example, introduced in the late eighteenth century *metallic tractors* that if drawn lightly over the affected body part for 20 minutes could cure local pains, rheumatism, inflammation, and tumors. Each tractor, one made of brass and the other of iron, was about 3 inches long, blunt at one end and pointed at the other. Perkins patented the tractors, traveled the world promoting them, and became rich during the three decades the idolators craved his gizmo.

Today, Perkins' tractors are in museums, not clinics. Despite establishing the Perkinean Institute in London in 1804, where his idolators could congregate and share uncritical tales of success, by 1811 the tractors were nearly forgotten. Forty years later Oliver Wendell Holmes described the tractors as a "rich and comparatively recent illustration of the pretensions, the arguments, the patronage, by means of which windy errors have long been, and will continue to be, swollen into transient consequence." He considered this just one example of the "superfluous abundance and the boundless credulity and excitability of mankind upon subjects connected with medicine."[4]

My first encounter with gizmo idolatry came early in my career, with a gift from my parents of a *violet ray device* they stumbled over in a flea market. Unaware of what the device did, or even its name, they purchased it because it was "medical" and they knew of my love for medical antiques. The device has a plastic handle, about 10 inches long and 2 inches wide, into which glass probes, conforming to different body part shapes, are inserted. The base contains a high-frequency Tesla coil that imparts a brilliant purple glow to argon gas in he probes, which emit ozone, ultraviolet light, and bountiful sparks that heat and sting the skin.

Violet ray devices were introduced at the World's Columbian Exposition in 1893 and were popular until the Food and Drug Administration (FDA) banned efficacy claims in 1951.[5] According to one manufacturer, the device was "absolutely harmless," could be used in the "most delicate invalid or child without the least fear of injury," and cured nearly 50 ailments including abscesses,

asthma, arteriosclerosis, baldness, brain fag, colds, deafness, female complaints, goiter, insomnia, obesity, sore throat, and weak eyes.[6] Today, the violet ray still has a following among cosmetologists, holistic therapists, and alternative medical practitioners.

So why would it take more than half a century to debunk medicinal claims of violet ray manufacturers? Most likely the device owed its incredible success as a gizmo to stimulating four of the five senses with reasonable safety: users could see the purple glow, smell the ozone, hear the coil hum, and feel the sparks tickle their skin. In addition, the device was portable, widely available, and reasonably priced. With all these wonderful attributes to induce placebo effects, whether or not it actually worked was largely irrelevant.

Evaluating Gizmos

What can we learn about gizmos from Perkins retractors and violet ray devices? Skepticism is timeless, but new paradigms of evidence-based medicine provide modern context for distinguishing unproven gizmos from safe and effective devices. Here are some questions to ask when evaluating a medical device:

1. *Is it approved?* Most devices are approved through the FDA 510(k) pathway, which allows marketing if "substantial equivalence" is shown to existing devices. The Institute of Medicine, however, strongly recommended eliminating this pathway because it *does not require* proof of efficacy or safety.[7] In contrast, only 1% of medical devices use the FDA premarket approval pathway, which does require such proof. When a device is used for an indication not in the approved labeling, it is "off-label" and the physician should say so and maintain records of its use and effects.[8]
2. *Does it work?* Since FDA 501(k) approval *does not* require proof that a device really works, approval does not imply effectiveness. Showing something "works" is best done through comparative studies and large case series in real-life settings with outcomes that patients care about. Popularity alone does not validate use (think Perkins' retractors and violet ray devices), because "popular opinion is the greatest lie in the world."[9] Devices that really *work* have valid and generalizable published research to support the claim.
3. *Is it safe?* Determining if new technology is "safe" is difficult because late or rare adverse outcomes may not be apparent for many years. Safety claims by innovative, early adopters on carefully selected patients in specialty settings may not translate into safety for less experienced clinicians. Even when clinical trials do exist, they are often too small (underpowered) to detect rare events. Data registries, if available, give more meaningful information. The only relevant safety information comes from asking the clinician how many cases and what adverse events or complications occurred.
4. *Are there conflicts of interest?* Bringing new technology to the bedside inevitably involves conflicts of interest,[10] including financial relationships between clinicians and device manufacturers that could impact decisions about use, safety, and effectiveness. Physicians, for example, may hold patents, receive royalties, have research funding from the manufacturer, or serve as "key opinion leaders," who receive speaking honoraria, consulting

fees, travel grants, or stock holdings. Ideally the raving fan clinician who recommends a device *should not* have financial conflicts, but if they do they must be solicited, disclosed, and duly considered.

5. *Is it worth it?* Just because a new device or technology is "FDA approved" does not guarantee coverage of costs by an insurer. Coverage is provided only for devices "medically necessary" to diagnose or treat a condition.[11] Even when necessity is suggested by clinical research, payment may not be forthcoming until the Centers for Medicare and Medicaid Services determine facility reimbursement and the need for any new billing codes, which can take up to 3 years with millions of dollars in costs. Advocates of a device should discuss cost and coverage up front, and patients need to decide if any out-of-pocket expenses are truly justified.

An ideal medical device, therefore, is FDA approved, has convincing safety and efficacy in research studies, is recommended by a clinician without financial conflicts of interest, and the device cost is covered (or at least largely covered) by the patient's insurer. To the contrary, look for a big, bright "Gizmo Alert" sign when a device is recommended off-label, has one small research study (kindly funded by the manufacturer) to support its use, has limited safety data with only short-term follow-up, is touted by clinicians who own patents or gain financially when the gizmo is used, and the majority of insurers deem it "medically unnecessary" and deny payment. Of course most devices fall somewhere in between these polar opposites, but the contrast is useful to illustrate how answers to the previous 5 questions permit systematic assessment of a medical device.

A Gizmo Parade

One of my favorite gizmos was the "OtoLAM," the "LAM" being short for "laser-assisted myringotomy." Introduced in the late 1990s, the laser could consistently punch a 2 mm hole in the eardrum to treat middle ear fluid. Aggressively promoted by the manufacturer and key opinion leaders, the device claimed to revolutionize ear disease by replacing ventilating tubes with a quick and painless office procedure. The device faded into oblivion after a few years because of questionable effectiveness, more pain than advertised (children would often not let the doctor do the opposite ear), and—most importantly—inability by the manufacturer to obtain a dedicated billing code that justify the $80 000 device cost. Later, the procedure was proven much less effective than traditional ventilating tubes.[12]

I recently saw several parents with breastfeeding difficulties who felt lip-tie (an excessive superior *label frenulum*) might be the source of their newborn's problems. My last literature review, a few years earlier, suggested lip-tie is often selflimited and warrants surgical repair only if it causes separation (diastasis) of the upper incisor teeth. A new search revealed some case reports and narrative review articles from experts calling lip-tie an underrecognized yet highly treatable cause of poor latch and painful breast feeding. The treatment, however, involved laser surgery with up to $1000 of personal expense since the procedures were off-label and not covered by insurers. Until research studies show benefits of laser frenectomy for lip-tie above and beyond watchful waiting, I would share the insurer's doubts about the benefits and, more importantly, the safety of this new use for an old gizmo.

Second only to ventilating tubes in terms of frequency, tonsillectomy has always been a gizmo magnet. Traditionally the tonsils are completely removed, but in the early 2000s surgeons used the surgical microdebrider to "shave," or partially remove, the tonsil, preserving the underlying capsule as a natural, protective bandage (intracapsular tonsillectomy). Key opinion leaders touted faster recovery, reduced pain, and enhanced safety (less bleeding and dehydration), based on observational studies, whose authors often had financial conflicts of interest. Randomized trials, however, showed no difference in hemorrhage and dehydration but did note a faster return to normal diet.[13] "Shaving" tonsils may be a reasonable alternative to tonsillectomy, but benefits seem overstated, the issue of remnant regrowth is unresolved, and the role of the procedure for an indication of recurrent infection is unclear.

Balloons are all the rage in treating ear, nose, and throat disorders. Experts use them to open clogged ears, blocked sinuses, and narrowed airways. Do they work? Possibly, but since they are approved through the FDA 510(k) process, proof of efficacy is not needed. Are they safe? Most likely, but rare events may still be forthcoming as more patients are studied with longer follow-up. Who benefits from balloons? Hard to say, because the studies often include highly selected patients, combinations of balloon and traditional surgery (hybrids),[14] and outcome measures that have questionable value (eg, nonvalidated surveys) or relevance to patients (eg, measures of sinus ostia patency). Bias from industry funding can also plague interpretation.

Gizmos and the Future

Lasers, shavers, and balloons have varying success in answering the 5 gizmo questions posed earlier, but they all share the seductive appeal of enhancing the surgeon's precision and accuracy, with theoretically improved outcomes. This creates a powerful marketing niche for manufacturers, driving existing technology to new audiences in different disciplines.15 The race is on when the "latest and greatest" mantra is combined with a 510(k) blessing from the FDA and utopian claims of safe, painless, and bloodless surgery with enhanced accuracy, precision, and outcomes.

Will today's gizmos still be around in a decade? Time will tell. What is certain, however, is that many gizmos now being heralded in the exhibit halls at medical meetings will fade away as efficacy is questioned, long-term data raise safety concerns, promotional funds wane, and the raving fan key opinion leaders find newer gizmos, earlier in their development cycle, to tout. The quest of fashion designer Coco Chanel seems strangely relevant: "Innovation! One cannot be forever innovating. I want to create classics."[16] A healthy respect for classics while cautiously embracing innovation would seem the best medical compromise.

Rosenfeld R. M., (2014). Gizmos. Otolaryngology - Head and Neck Surgery 150, no. 4 p.505-508. Reprinted with permission by SAGE Publications, Inc.

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Gizmos Is a Mean Word! (Response to Rosenfeld Editoral)

Peter J. Koltai

Abstract

The editorial titled ''Gizmos'' in the April issue of Otolaryngology–Head and Neck Surgery was unfortunate. Intracapsular tonsillectomy is a rational surgical option for managing tonsillar hypertrophy causing obstructive sleep apnea in selected children. It is performed routinely by sur- geons across the globe and has become the standard of care across northern Europe due to the high safety profile of the operation. The semirigid, dartlike design of the sinuplasty devices suggested the idea for an airway-specific set of high-pressure balloons. We began working on these in 2007 and had FDA approval in 2009. They are in wide use by

many airway surgeons. Lingual tonsils are a frequent cause of obstructive sleep apnea, and there is no tool that manages this as effectively as endoscopic plasma ablation. We are all engaged in an honorable effort to improve care; surgical and creative skills are as important as analytical skills. Both are necessary for the continuous improvement of our work. Both are worthy of respect.

When I saw the editorial titled ''Gizmos'' in the April issue of Otolaryngology–Head and Neck Surgery,[1] I thought, ''That is an unfortunate word.'' After starting to read the article, I had a sense that intracapsular tonsillectomy would be one of the targets, and indeed I was not disappointed. However, I was surprised when I saw that high-pressure airway dilation balloons and plasma ablation were included as well. Given the unkind nature of the editorial, I felt I should respond. For the sake of full disclosure, I have had a royalty agreement for the design and development of an FDA- approved microdebrider for intracapsular tonsillectomy and adenoidectomy. I was also involved in the design and development of the FDA-approved high-pressure airway balloons and continue to work on the next generation of these devices. We have been using plasma ablation for lingual tonsillectomy for the past decade,[2] and this does not have specific FDA approval. I have had modest profit from and great pride in the wide acceptance of these tools into our surgical armamentarium.

A little history will help here. In 1993, I saw the first demonstration of the use of a microdebrider for endoscopic sinus surgery by Dr. Ruben Setliff, who had conceived the technique. He used an instrument that had been developed for temporomandibular joint (TMJ) arthroscopic surgery. The device had failed as a treatment for TMJ pain, but it was revolutionary for sinus surgery and its use rapidly spread; it didn't take randomized controlled studies to convince most of us of this new tool's utility. Another device manufacturer had a microdebrider line for arthroscopy and had patented a bendable blade that we found an elegant tool for shaving adenoids from the nasopharynx.[3,4] In 1996, after considerable experience performing powered adenoidectomy, I saw an 11-month- old infant who was failing to thrive due to tonsillar and adenoidal hypertrophy causing severe obstructive sleep apnea (OSA), with a high apnea hyponea index and significant desaturations. The child failed aggressive medical management. Given our positive experience with the microdebrider for lymphoid tissue, and being familiar with the history of tonsillotomy and knowing how challenging a tonsillectomy would be for such a young child, I proposed an intracapsular tonsillectomy to the parents, and after appropriate consultation and discussion they accepted. The surgery was quick and uneventful. The postoperative recovery was rapid and remarkably benign. After our encouraging first experience, we cautiously started offering this procedure but confined our indication to very young children with severe OSA who had large exophytic tonsils, aware that we were challenging a century of tonsillectomy tradition. As our experience and confidence with the technique grew and I after I became aware of the work of Elizabeth Hultcranz in Sweden,[5,6] we began publishing our work in 2001,[7-9] causing considerable controversy that continues today.

Many studies have been conducted on the subject of intracapsular tonsillectomy, and I recognize and acknowledge the variability of the results reported in the literature. Nevertheless, with a personal experience of well greater than 1000 cases, I have yet to see a child with a postintra- capsular tonsillectomy bleed that required a trip back to the operating room to control hemorrhage. Our rates of post- operative recovery time have remained about half as long as for a total tonsillectomy, which, incidentally, I continue to perform regularly when indicated. Our regrowth rate has been remarkably consistent at 0.5% for the past decade. Intracapsular tonsillectomy is a rational surgical option for managing tonsillar hypertrophy causing obstructive sleep– disordered breathing in selected children. It is performed routinely by senior surgeons across the globe and has become the standard of care across northern Europe due to the high safety profile of the operation.

The history of airway dilation is more than 150 years old, and high-pressure balloons have been used for this purpose since 1984.[10] Our early experience with airway balloons began with devices originally intended for angioplasty, which were awkward in the airway. In 2005, I saw the first sinuplasty balloons at the fall AAO-HNSF meeting in Los Angeles. The semirigid, dartlike design of these devices suggested the idea for an airway-specific set of high-pressure balloons. We began working on these in 2007 and had FDA approval in 2009. It would be interesting to see how many airway surgeons would prefer to do without this technology.

Finally, solid data have emerged concerning the variable success rate (50%-80%) in the effectiveness of adenotonsillectomy for the management of pediatric sleep apnea. Our work over the past decade has focused on these failures. Our primary tool in diagnosis of the site of persistent obstruction has been the use of drug-induced sleep endoscopy. An important observation has been the importance of the lingual tonsils and the retrusion of the tongue base as a frequent cause of failure. Managing this problem was difficult until we worked out an endoscopic technique of using plasma ablation to remove the lingual lymphoid tissues. I know of no other tool that does this as effectively.

Now back to the unfortunate editorial. Gizmo is a mean word, a pejorative word, a word connoting frivolousness, even dishonesty. While there is no denying there are plenty of ‘‘gizmos’’ out there, even for the sake of rhetoric it is disingenuous to compare the ‘‘violet ray device’’ to thoughtfully engineered instruments that are successfully used internationally for managing difficult surgical problems.

Our specialty is strong because among us we have many diverse skills. Ingenious analytical skills and creative surgical skills are important, yielding evidence and experience, the yin and yang of our craft. Both are necessary for opening the gates of perception a little wider for all of us. Both are necessary for the continuous improvement required for the safety and quality of our work. Both are worthy pursuits. Both are worthy of respect.

Peter J. Koltai, (2015). Gizmos is a mean word! Otolaryngol Head Neck Surg April 2015 vol. 152 no. 4 p. 581-582. Reprinted with permission by SAGE Publications, Inc.

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Gizmos Revisited (Response to Koltai)

Richard M. Rosenfeld

As editor in chief of Otolaryngology–Head and Neck Surgery, I wrote 35 editorials on critical thinking, evidence- based medicine, and related issues.[1] All use a fictitious, tongue-in-cheek letter to the editor as a springboard for a light-hearted discussion that is intended to be informative, entertaining, and provocative. Judging from Dr Koltai's commentary,[2] I clearly accomplished the last goal with my editorial on gizmos.[3]

Dr Koltai considers gizmo to be a mean, unfortunate, and pejorative word that implies frivolousness and dishonesty. None of this is suggested in my editorial. The term is instead used to describe a medical device, typically with complex technology (eg, bells and whistles), touted by early adopters, which may or may not over time (perhaps even decades) demonstrate the safety and efficacy initially promoted. Beyond the editorial, many individuals (myself included) use gizmo to describe the panoply of expensive gadgets used by otolaryngologists in the office and operating room.

Otolaryngology is chock full of gizmos (as just defined), which can be seen with even a brief stroll through the OTO EXPO exhibit hall at the Annual Meeting of the American Academy of Otolaryngology—Head and Neck Surgery Foundation. These gizmos and gadgets add fun to the daily practice of Otolaryngology and likely contribute to its popularity as a career choice. Moreover, many of them facilitate safe and effective patient care that would otherwise not be possible; they have withstood the test of time and the critical eyes of clinicians and payers worldwide.

My purpose in writing the ''gizmo'' editorial was to remind readers that all that glitters is not gold and that medical devices are subject to the same laws of statistical and epidemiological gravity that govern other interventions. This caveat is important because of the inherent appeal and attractiveness of gizmos, which sparked a commentary titled ''Gizmo Idolatry'' by Leff and Finucane.[4] As noted in my editorial, an ideal medical device ''is FDA approved, has convincing safety and efficacy in research studies, is recommended by a clinician without financial conflicts of interest, and the device cost is covered (or at least largely covered) by the patient's insurer.''[3]

In response to Dr Koltai's commentary, I reread my original editorial and could not find anything pejorative, nor could I find anything to support his claim that I ''targeted'' with an ''unkind nature'' intracapsular tonsillectomy, airway dilation balloons, and plasma ablation. Plasma ablation is not even mentioned in the editorial, intracapsular tonsillectomy is used as an example for which observational studies show larger benefits than randomized trials, and balloons (in the sinuses and airways) are briefly mentioned to illustrate the FDA 501(k) approval process, which does not require demonstration of efficacy, only equivalence to existing alternatives. What I do state is that questions remain regarding indications and efficacy that should prompt a thoughtful approach when using these and other devices.

I acknowledge Dr Koltai's contributions to worldwide Pediatric Otolaryngology. His novel and innovative work with intracapsular tonsillectomy and airway balloon dilation has benefited many children and inspired robust presentations and debate. The ultimate fate of these and other medical devices (gizmos, gadgets, or whatever you call them), however, rests with trustworthy research showing safety and efficacy in diverse practice settings, not simply enticing technology that ''makes sense'' and has many proponents. Truth takes time to operate,[5] and perhaps nowhere is this more true in medicine than with gizmos.

Rosenfeld R. M., (2015). Gizmos. Otolaryngology - Head and Neck Surgery April 2015 152: p. 583-584. Reprinted with permission by SAGE Publications, Inc.

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