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Digital Therapeutics in Hearing Healthcare: Evidence-Based Review

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Digital therapeutics (DTx) in hearing research have emerged as a new category of therapies providing evidence-based intervention via digital means, such as software, smartphone apps, or websites. However, although relatively new, they are not well-established. In this article, we review DTx technologies in hearing research fields, focusing on three categories: prevention and diagnosis, aid (assistance), and cure (digital medicine). We observe that most DTx systems require interactions with users (or patients) without the direct support of clinical professionals to obtain or collect medical evidence; this makes training (or education) features crucial to the therapy's success. In this view, this article discusses the education or training functions of the current DTx and their contribution and purposes. The impact of emerging artificial intelligence (AI) on DTx in hearing research is being explored, and the future of DTx concerning AI integration is being discussed. We believe that this work will contribute to a better understanding of the current and future DTx technological advancements and, in particular, shed light on the field of hearing research. **J Audiol Otol 2024;28(3):159-166**

Keywords: Digital therapeutics in hearing research; Digital therapeutics; Artificial intelligence DTx.

Introduction

The term "digital therapeutics (DTx)" was coined through the collaborative efforts of researchers. It began to see widespread use around 2012 and first appeared in a research publication in 2015 [1]. The DTx are software and/or hardware products aiming to operate medical interventions independently and serve the functions of diagnosing, treating, preventing, and managing health conditions. They can be accessed through hardware devices such as smartphones, tablets, virtual reality (VR) headgear, cameras, webcams, and others. US Food and Drug Administration (FDA) approvals are needed if they expose medical effects or deliver clinical outcomes to prove safety and effectiveness before being commercially accessible. However, digital health concepts in DTx emphasizing general well-being may not require regulatory oversight.

Approved American National Standards Institute (ANSI)/Consumer Technology Association (CTA) put efforts to establish standards for DTx and announced ANSI/CTA-2098 [2]. They list the DTx purposes into six random categories: 1) medical intervention, 2) delivery, 3) disease, disorder, or other condition, 4) management, maintenance, prevention, or treatment, 5) standalone and combination, and 6) evidence-based. The DTx can be seen as a subgroup of "digital health technology (DHT)," but there is no formal definition for the DHT developed by the FDA or other government agencies, so they review other industry-related terms to the DTx to establish the standards under the DHT umbrella.

It is worth considering the advantages/disadvantages of the DTx for better utilization. The benefits of DTx are reduced cost and easier access to preferred environments, especially for people with behavioral health problems, youth, rural areas, LGBTQ+ (lesbian, gay, bisexual, transgender, queer or questioning, intersex, asexual, and more), and others. It also provides relief from the lack of a workforce, but it has to be mentioned that the DTx is not intended to replace primary medical providers/doctors. They do not require (or do not have) a prescription; the FDA approves/clears prescription use in the United States. In fact, a lot of mobile apps for behavioral health do not come with a prescription or approval. The DTxs are limited to people who are uninsured, underinsured, or have limited internet access. Privacy and security protection are strictly required functions at a product level; although the aim is to pass a rigorous amount of research and testing, there is a variation in the amount of investigation in each product, even under the same medical level/class.

The current major field of DTx applications is behavioral health, but DTx is growing fast in other healthcare areas, especially after COVID-19, including the hearing research field. The recent research surge in machine learning (ML)/artificial intelligence (AI) and computing power have contributed to DTx growth significantly [3], but the AI applications in hearing research DTx are still lean [4]. Hearing matters for the life quality. There has never been a treatment for hearing problems that is considered to be definitely sufficient and effective. The DTx, software and/or hardware systems for hearing include adjusting hearing aids remotely, running online auditory training, and much more. It is accomplished through the optimization of existing treatments using advanced algorithms or machine learning to develop new approaches to hearing-related issues.

This review paper focuses on DTx technologies and applications in hearing research fields. Particularly, this review examines emerging cutting-edge DTx devices, applications, and technologies developed into three categories: 1) hearing problem prevention and diagnosis, 2) hearing assistance (aid), and 3) hearing disease treatment (curing). Also, we discuss education and training features of the DTx in hearing research fields; the majority of DTx involve education or training procedures due to the nature of therapy done by oneself without the direct aid of professionals or oneself who is new to the digital systems. The purposes of the procedure can be, but are not limited to, training clinicians to get familiarized with the DTx systems to instruct their patients and more. The remaining pages will discuss the education/training aspects of the DTx systems followed by DTx in hearing research outlook with AI applications and the conclusion of this paper.

DTx Categories in Hearing Research

The DTx is a new emerging topic, especially in the field of hearing care research. Modern digital means such as smartphones, cameras, sensors, personal computers, and/or smart devices integrate with smart software to provide dedicated functionalities for preventing, diagnosing, curing, or assisting human hearing matters. Oftentimes, the integrated system is connected to local or wireless networks to collect/store subject data or to communicate with healthcare professionals for further investigation.

In this section, we review the DTx in hearing research based on the suggested taxonomy: 1) prevention and diagnosis of hearing matters, 2) hearing assistant or aid, and 3) digital medicine to cure hearing disorders.

Prevention and diagnosis

Table 1 lists the DTx technologies in hearing research to focus on the prevention and diagnosis of any hearing symptoms. In the prevention and diagnosis category, ML and AI are of high interest. Traditional diagnosis in clinics heavily relies on past data and classifies medical conditions [5], focussing on similarities between patients, and idiographic inference. This role can be replaced by ML models that can learn from historical data and handle classification tasks, solving time consumption in the current diagnosis. To manage communications between patients and ML models, hardware devices are provided to complement the diagnosis process as a medium to deliver data to software.

Barbour, et al. [6] present online audiometry using ML—machine learning audiogram (MLAG). The MLAG has the potential for unbounded prediction due to its ML basis (compared to the classic Hughson-Westlake audiogram [HWAG] procedure), but at the same time, it has problems with limited data samples. Angley, et al. [7] introduce remote audiology services such as otoscopy, various diagnostic tests, hearing aid fittings, newborn hearing screenings, cochlear implant mappings, and real-ear measurements. Distance support (DS) software was used for both in clinic and in-home appointments by participants communicating with the audiologist via a clinic landline telephone. Participants were given a study laptop, DS package, USB stick, hearing aids, and a web camera for in-home appointments. Besides the main diagnostic and prevention purposes, this DTx application also serves as a teleclinic. Ezzibdeh, et al. [8] developed an ML model for otoscopy with a hardware CellScope consisting of an iPhone case scaffold, an otoscope head, and an ear speculum. With high accuracy and speed, otoscopic image classification has significantly improved otolaryngology, particularly in diagnosis. A Software Intelligent System (SIS) is demonstrated by Rajkumar, et al. [9] that performs audiological investigations, assesses the degree of hearing loss, and suggests appropriate hearing-aid gain values with neural networks. Kobewka, et al. [10] created the SHOEBOX QuickTest app, an iPad-based app for hearing screening for older adults. Screening is done

Table 1. DTx technologies in hearing research: prevention and diagnosis of hearing symptoms

Study	Year	Device platform	Target disorder	Highlights
Barbour, et al. [6]	2019	Online (website)	Hearing loss	Online, machine learning based audiogram
Angley, et al. [7]	2017	Online (website) +Physical device	General hearing disorder	Providing remote audiology services such as otoscopy, diagnostic tests, hearing aid fittings, newborn hearing screenings, cochlear implant mappings, and real-ear measurements
Ezzibdeh, et al. [8]	2022	Online (website) +Physical device	General hearing disorder	Performing ML with otoscopic images to classify hearing disorder diagnosis
Rajkumar, et al. [9]	2017	Online (website)	Hearing loss	A software intelligent system based on neural network for classification of hearing loss level and suggestion of hearing-aid gain values
Kobewka et al. [10]	2023	iPad app	Hearing loss	An app called "SHOEBOX QuickTest" for hearing screening
Convery, et al. [11]	2020	Mobile app	Hearing loss	An app called "ReSound Smart 3D" which enables remote hearing aid adjustment
Gupta, et al. [12]	2021	iOS+Android app	Hearing loss	An app called "noise-induced hearing loss (NIHL)," which enables real-time assessment of audio and ambient sound exposures especially military situations

by users responding (clicking the circle on the screen) to a sound they hear in the app. Convery, et al. [11] assessed ReSound Smart 3D hearing aid app. The app communicates with the hearing aid via Bluetooth to make adjustments to the user's hearing aid. By responding to questions from the app messages, users can request clinician adjustments to their hearing aid settings. The clinicians then create customized settings based on the user's responses, which are sent back to the app. Users can download the new settings created by the clinicians, and the settings will automatically be reflected on hearing aids. Gupta, et al. [12] introduced Hearing Health App for real-time assessment of audio and ambient sound exposures, especially in military situations, compared to the US and United Nation (UN) safe standards to assist in reducing risks of noise-induced hearing loss (NIHL). The app's functionality includes tracking noise dosage, running sound exposure assessment, alerting, informing, personalized setting, and sharing exposure reports to others.

Aid (assistant)

Table 2 lists the DTx technologies in hearing research that focus on aiding or assisting purposes for any target hearing-related disorders. The majority of DTx in this aiding category work as supplemental sensory aids. Examples include sound classification and speech recognition systems, which notify users of this information via mediums like micro-displays on smart glasses [13]. Some more advanced aiding DTx utilize gesture recognition from wearable devices to transcribe motions and enable communication [14]. Other aiding DTx take the form of instructional software applications containing educational programs meant to teach skills like lip reading and sign language through instructional videos [15]. Some DTx in this category also serve as temporary assistance tools for living, providing comforting sounds or affecting hearing frequencies to improve the quality of living conditions [16].

Tinnibot designed by Roberts, et al. [17], is a chatbot platform specific for adult tinnitus patients. It is accessed online through smartphones, tablets, and personal computers. It aims to manage patients' behaviors and attitudes towards tinnitus, to run meditation, and to play sounds for better sleep. The platform may help mitigate the disease symptoms but not as the primary purpose [17]. It may not be categorized as DTx platform, but Le Prell, et al. [16] introduce an interesting experiment to be adopted in DTx. The experiment reveals that music that can be accessed via any form of modern devices, such as iPods, can influence people's temporary threshold shifts (TTS). Although their experiments ran only on subjects with normal hearing and TTS is a temporal phenomenon, the results infer that listening to music could also be utilized as a digital medicine for curing purposes in the future. Balling, et al. [18] introduce personalized sound optimization for hearing aid users using Widex SoundSense Learn (SSL) with A-B comparison based on active learning. This method aims to make hearing aids capable of adjusting and optimizing their functionality for specific users via ML technologies, understanding that most hearing aids are built for general types of hearing loss. Siddiqui, et al. [19] developed an open source app for scene (sound) classification of surrounding environ-

Table 2. DTx technologies in hearing research: aid and assistance for target hearing disorders

Study	Year	Device platform	Target disorder	Highlights
Shoaib, et al. [1]	2018	Software	Hearing loss	Software for lip reading education designed for hearing impaired children
Le Prell, et al. [16]	2012	Software	Hearing loss	Introducing software to change temporary threshold by exposing to music
Roberts, et al. [17]	2023	Online (website)	Tinnitus	Online chatbot called "Tinnibot" for managing patients' perception, meditation, and sleep support with specific sounds
Balling, et al. [18]	2021	Software with hearing aids	Hearing loss	A software product with hearing aids called "SoundSense Learn" which performs active learning to optimize automatic sound detection
Siddiqui, et al. [19]	2022	iOS app	Hearing loss	An app called "deep neural decision forest (DNDF)" which enables classification of surrounding environment and parameter tuning of hearing aid settings
Young, et al. [20]	2020	Micro-display on glasses, training on PC	Hearing loss, deafness	A system provides transcription, alerts traffic or other potential dangers from sounds via Internet of things, speech recognition, and sound classification technologies
Jongeneel, et al. [21]	2022	iOS+Android app	Auditory hallucinations	An app called "Temstem" which enables auditory verbal hallucination inhibition
Mishev, et al. [22]	2022	Online (website)	General hearing disorder	Online and cloud-based text-to-speech synthesizer
Aldaz, et al. [23]	2016	Mobile app (Android)	General hearing disorder	And app called "Hearing Aid Learning and Inference Controller (HALIC)" which enables self-training of hearing aid's gain-frequency response and compression parameters in everyday situations
Chong and Jenstad [24]	2018	Software in hearing aids	Hearing loss	Introducing modulation-based noise reduction software for hearing-aids especially for fricatives
Seol, et al. [25]	2021	Mobile app	Hearing loss	An app for sound amplification with the help of augmented reality
Adamo-Villani, and Wilbur [26]	2010	PCs, Xbox360, four-wall projection, fish tank VR, head mounted display	Hearing loss	3D animation learning software for math concepts and signs through American Sign Language (Mathsinger: 3D animation; SMILE: virtual reality)
Zhou, et al. [27]	2020	Software and wearable device	General hearing disorder	A software with wearable sensors to enable finger-gesture recognition providing sign-to-speech process
Maruthurkkara, et al. [28]	2022	Mobile app	Cochlea implant	An FDA approved telepractice solution called "Remote Check" to allows clinicians to promptly assess the patient status

ment and parameter tuning of BioAid (The Biologically Inspired Hearing Aid) settings; the app is designed for patients with mild to moderate hearing loss. The classification is done with a deep neural decision forest (DNDF), combining convolutional layers and a decision forest as the final classifier, and the result is reflected on the settings for hearing aids [19]. Young, et al. [20] presented an AI-enabled Internet of things (IoT) device for hearing loss and deafness. Google's speech recognition with micro-displace on glasses enables transcribed texts on the glass, and the urban-emergency classifier alerts traffic or other potential dangers. The models are optimized with transfer learning, training the last layer with the user environment through IoT from the user's PC and accessing Google's speech recognition model on the cloud [20]. Jongeneel, et al. [21] conducted evaluation of Temstem, an app for patients suffering from auditory verbal hallucination (AVH). The app consists of two functions; Silencing (inhibition) and Challenging (dual tasking). In the Silencing function, users play a language game in order to temporarily suppress any voices they may be hearing. This function was derived from the finding that actively producing incompatible sounds or language prevents one from hearing voices. The Challenging function seeks to intervene and reduce the salience and frequency of AVH by taxing the working memory with a language game during the recall of a negative voice statement. Engaging in this cognitive task significantly lessens the emotionality, vividness, and credibility of the hallucination [21]. Shoaib, et al. [1] introduced LOSINA (Learning Application without Sign Language for Profound Hearing Impaired Children) which is a learning application without sign language for profound hearing-impaired children. The LOSINA is an interactive software application that contains video demonstration of lips and mouth movements to show pronunciations of words, aiming to improve articulation of words. Mishev, et al. [22] designed MAKEDONKA, a cloud-based text-to-speech synthesizer for visually-impaired and hearing-impaired students. The hearing impairment module offers a video demonstration of Macedonian sign language service. Aldaz, et al. [23] evaluated the Hearing Aid Learning and Inference Controller (HALIC). It is a system with an Android smartphone app to enable users to conduct self-training on hearing aid's gain-frequency and compression parameters. The system consists of smartphone sensors for user data collection, a graphical user interface, and ML processing (reinforcement learning). The system addresses the limitations of modern hearing aids in learning user preferences: limited sensor inputs (only two onboard microphones), restricted user interface, and low processing power, which prevents the implementation of ML algorithms [23]. Chong and Jenstad [24] focused on digital noise reduction in hearing aids, enhancing speech intelligibility, especially in noisy environments for the fricatives. This research contributes to the ongoing advancements in signal-processing technologies aimed at improving speech understanding for individuals with hearing loss. Seol, et al. [25] examined the effectiveness of hearing aids (HAs), personal sound amplification products (PSAPs), and wearable augmented reality devices (WARDs). Examples include ReSound LiNX Quattro (HA), Etymotic Bean (PSAP), and Samsung Galaxy Buds Pro: Galaxy Wearable app, ambient sound (WARD). Software named Mathsinger was developed by Adamo-Villani and Wilbur [26]. The Mathsinger is a learning platform for math and American Sign Language through 3D animation for deaf children, their parents, and teachers. The research also presented SMILE, a responsive VR learning software for STEM (science, technology, engineering, and mathematics) concepts. The VR environment can be accessed through four-wall projection, single screen projection, fish tank VR, desktop computers, and head-mounted display [26]. It is worth mentioning about DTx research that ear healthcare is not its primary purpose, but it still aids hearing-disabled people. Zhou, et al. [27] developed a finger-gesture recognition system (wearable sign-to-speech translation model) for speechless communication to aid people who experience hearing disorders. Remote Check is the first telehealth assessment tool that is FDA-approved device for cochlear implants, enabling self-testing and asynchronous access. It serves as a convenient at-home testing tool for cochlear implant recipients using an app on their mobile device. It lets users test their hearing and send the results to their clinic and the clinicians use this info to see how the patient is doing with their hearing and if they need more help. This approach supports efficient patient management, reduces unnecessary clinic visits, and addresses the growing demand for audiological telepractice in long-term care for cochlear implants recipients [28].

Digital medicine (cure)

This curing category collection is slim due to the physical challenges involved in curing hearing-related diseases. Table 3 lists the DTx technologies in hearing research to cure or improve hearing disorders. Note that this category can be seen as digital medicine in hearing health care, which is believed to mitigate the condition and different from the DTx assistance function. Currently, there are not DTx designed to prescribe for addressing hearing loss. However, in the realm of digital health, efforts are ongoing to develop programs for hearing evaluations, speech therapy, and auditory training. Most curing purpose DTx comprises online auditory training programs or apps aiming to improve hearing conditions. The majority of training programs depend on the human ear and brain plasticity; the nervous system manages a certain level of challenges or stimuli by recognizing its structure, functions, or connections. "Amptify DTx" was created by Tye-Murray, et al. [29], an online program for auditory training via video games for hearing loss. The program can be accessed on the website and is available for both mobile phones and computers. "Hear Me Read" app was developed by DeForte, et al. [30]. It is a therapy tool for children who have complex speech, language, and literacy issues with hearing loss. The app is built on iPhone OS and contains interactive digital storybook reading, syntax highlighting, and audio-visual features, including video recording and playback functionalities. A therapist mod is available to create individual therapeutic language and to set up literacy goals. "Software Auxiliar na Reabilitação dos Distúrbios Auditivos (SARDA)" is designed by Silva, et al. [31]. It is an auxiliary software for the rehabilitation of hearing

Table 3. DTx medicine for curing and improving hearing disorders

Study	Year	Device platform	Target disorder	Highlights
Tye-Murray, et al. [29]	2022	Online (website)	Hearing loss	Online programs called "Amptify DTx" for auditory training via video games for hearing loss
DeForte, et al. [30]	2020	iPhone OS app	Hearing loss	An app called "Hear Me Read" which is a therapy tool for speech, language, and literacy for children with hearing loss through digital stories
Silva, et al. [31]	2012	Software	Hearing loss	Auxiliary software called "Software Auxiliar na Reabilitação dos Distúrbios Auditivos (SARDA)" for the Rehabilitation of hearing disorders for children
Martin [32]	2007	Mobile app+online (website)	Hearing loss	A system called the "Listening and Communication Enhancement (LACE)" which is individual-based software for enhancing communication through auditory training with US and UK English styles
Ratnanather, et al. [33]	2021	Mobile app+online (website)	Hearing loss	Mobile health app called "Speech Banana" for auditory training
Vitti, et al. [34]	2015	Online (website)	Hearing loss	An online application system called "SisTHA" which is for auditory self-training
Buechner, et al. [37]	2022	Wireless headphone +intra-oral device	Tinnitus	A system called Lenire, an FDA approved bimodal neuromodulation that uses sound and electrical stimulation on the tongue to treat tinnitus

disorders. The software is used during the course of hearing-impaired children's treatment to improve learning and language difficulties. The SARDA can also stimulate the auditory abilities of normal hearing levels. The software contains six strategies, each containing a different auditory approach, such as a memory game of auditory stimuli [31]. "Listening and Communication Enhancement (LACE)" program was made by Martin [32], which is for an individual-paced software for enhancing communication through auditory training. The program practices speech in noise, rapid speech, auditory memory, competing speakers, and context used for hearing-impaired listeners [32]. "Speech Banana" app is designed by Ratnanather, et al. [33], a mobile health app or mHealth for auditory training. The app provides an auditory training curriculum in English and Korean languages with a simulation of in person auditory training through recorded voice. Vitti, et al. [34] demonstrated "SisTHA portal." It is a web-based auditory self-training system consisting of two modules: an information module (hearing aids guidelines) and an auditory training module for the rehabilitation of adult and elderly hearing aid users. Auditory training comes with six different levels of difficulties, where users need to correspond images shown on a computer screen and recorded sound. The reliability of the DTx in this curing category is worth noting. Olson [35] reviewed auditory training using digital mediums such as PCs or smartphones and suggest being cautious about using mobile apps for hearing therapy if it is compatible with medical standards or calibration. Almufarrij, et al. [36] reviewed 187 remote hearing assessment tools; they concluded that only 12 are peer-reviewed and 14 are acceptable. The majority tools' accuracy and reliability remain unknown, with tone-producing tools providing approximate hearing thresholds but having calibration and background noise issues. Speech and self-report tools are less affected but do not provide an estimated pure-tone audiogram. As evidenced by the number of reviews in this category, DTx solutions heavily rely on cognitive behavioral therapy, and there are only a few rising emergence of FDA-approved applications that are prescribed for use. Buechner, et al. [37] examined the effectiveness of Lenire, an FDA-approved device for sound stimulation through wireless headphones and electrical stimulation to the tongue via dental device. The device accomplishes bimodal neuromodulation, which combines sound and electrical stimulation of nonauditory peripheral nerves to improve tinnitus symptoms by driving neural plasticity and modulating the reticular activating system of the brain [37].

Discussion

Training and education

The typical DTx requires education or training procedures. The training and education procedure has two purposes. The first is for training clinicians to get familiarized with the DTx systems to instruct or diagnose their patients or for training patients if the therapy needs to be done by oneself without the direct aid of professionals. For example, "CellScope" is an iPhone-based otoscope used for visualization/diagnosis and education for clinicians [38]. Another purpose is pre-prescription or preparation before fitting or applying devices to human subjects. The hearing-aid device alone does not provide an optimal solution for hearing-loss ears. Additional training helps for both better device recognition in the brain and for the best device performance [35]. This type of training can be characterized as curing hearing disorders, as discussed in the previous section.

DTx in hearing research outlook with AI

The DTx technologies in hearing healthcare and research have benefited from recent AI advances, but compared to other research fields, its progress is limited [4]. Classification is the most popular AI-assisted task in DTx: examples include classifying otoscopic images with convolutional neural network (CNN) for diagnosis and sound detection/noise removal in the hearing aid [14,39]. Another usage of machine learning is optimizing hearing aid parameters through active learning, such as Bayesian optimization [40].

One characteristic of DTx being different from classic medical diagnoses/treatments is its accessibility and adaptability. There is no doubt about AI future success in DTx; still, limitations include weak infrastructure for users to collect and upload their data to customize models, lack of overall data for hearing-related healthcare, and absence of knowledge for ML applications in both users and clinicians. The ideal design of ML-based DTx should be transferable and learnable, meaning the product is adaptive to each user's environment. Developing new ML technologies for faithful replication of the auditory system is required to optimize the AI potential in hearing research. The transformation of hearing healthcare with AI technologies will not be easy because of ethical considerations and inertia associated with the current service system. When AI specialists work hand in hand with hearing researchers, the collaboration can pave the way for technology that truly enhances the lives of humans by addressing their unique challenges and preferences.

Conclusion

This paper reviews DTx advancement in hearing research with three main categories: 1) prevention and diagnosis, 2) aid or assistance, and 3) digital medicine or curing purposes. We also discuss training and education functions in hearing healthcare DTx and AI applications with the technology outlook. DTx is an emerging and applicable topic in all healthcare fields. We believe an inter-, multi-, cross-, trans-disciplinary approach with AI and the hearing research communities can create dramatic and compromising success and growth in the hearing health care DTx.

Conflicts of Interest

The authors have no financial conflicts of interest.

Author Contributions

Conceptualization: Noori Kim. Formal analysis: Keisuke Alexander Nakamura. Funding acquisition: Noori Kim. Investigation: Keisuke Alexander Nakamura. Methodology: Keisuke Alexander Nakamura. Project administration: Noori Kim. Supervision: Noori Kim. Validation: Noori Kim, Keisuke Alexander Nakamura. Writing—original draft: Noori Kim, Keisuke Alexander Nakamura. Writing—review & editing: Noori Kim. Approval of final manuscript: Noori Kim, Keisuke Alexander Nakamura.

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