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JRRD Guest Editorial

Cochlear prostheses: *L'enfant terrible*[*] of auditory rehabilitation

Born in controversy.
Raised in dogged determination.
Matured in grace and glory.

In the history of science, it is not uncommon for a major advance to be opposed, initially, by the scientific establishment. So it was with cochlear prostheses. The reasons for the initial opposition were not hard to find. Several early proponents of cochlear prostheses made pie-in-the-sky claims that leaders of the scientific community scornfully dismissed. Not all proponents of cochlear prostheses exaggerated claims and not all leading scientists opposed this unorthodox approach to the treatment of hearing loss, but a degree of hostility existed that had unfortunate consequences.

The passage from pie-in-the-sky concept to down-to-earth implementation is seldom traversed easily. The navigation on such historic journeys is invariably eccentric with many a false start. The eccentricities of navigation, however, were minor compared with the unbounded eccentricities of the navigators. I was privileged to witness this remarkable journey from a unique vantage point, and I hope in this editorial to convey some of the excitement of the journey and its relevance to the current and future development of cochlear prostheses. The articles in this special issue report on a continuation of this journey, but unlike the perilous beginning, traction is now on terra firma and with more than one vehicle exploring new horizons.

OBSERVATIONS OF A FLY ON THE WALL

Scientific articles provide considerable information, but in the vernacular of science. Statements are carefully phrased with caveats appropriate for readers pedantic. In this vein, scientific articles mask the excitement of discovery. Any hint of such by the authors is considered inappropriate, much like a public display of emotion by a stoic. It is one thing for a physicist to describe how the refraction of light through raindrops produces an optical filter in which light rays occupy contiguous spatial bands depending on their wavelengths. But if the physicist were to describe how the beauty of the rainbow affected his inner soul, this description would be considered akin to pornography in a scientific journal. This emphasis on physical facts with little empathy for the beauty of electrically induced sound, crude but audible, as heard by a deaf person, helps account for the initial divide between proponents and opponents of cochlear prostheses.

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[*]A usually young and successful person who is strikingly unorthodox, innovative, or avant-garde (Merriam-Webster, definition 2).

Once the value of cochlear prostheses had been demonstrated with adults, another bitter divide emerged regarding the ethics of implanting cochlear prostheses in children. The controversy involves deeply held beliefs regarding the relative importance of speech in deaf culture. The focus of this special issue of the journal is on cochlear prostheses for postlingually deafened adults (veterans), and consequently, the controversy surrounding the implantation of cochlear prostheses in children is not addressed here.

This is an editorial, not a scientific article. I have license to report on the excitement generated in the development of cochlear prostheses, as well as on the determination and perseverance of the dedicated scientists who pursued their dream against much opposition: *per ardua ad astra*.*

My first encounter with this curious breed of scientists was in October 1964 at the 68th Meeting of The Acoustical Society of America. I had graduated a few months earlier, and this was my first professional meeting in the United States. I was thrilled to meet so many famous scientists whose articles I had read assiduously as a student. The highlight of the meeting came when my boss, Jim Flanagan, asked me to join him for dinner with Blair Simmons. The discussion at dinner was mind-boggling. Blair Simmons had recently implanted a human being with six gross electrodes in the modiolus portion of the auditory nerve. This was 8 years before the science fiction novel *The Terminal Man* was written, and here we were talking about a live human being with electrical wires coming out of his skull, and if you applied an electrical signal to these wires, this deaf person was able to hear sound. All this was real but unbelievable.

Blair Simmons was not the first to stimulate the human auditory nerve electrically. André Djourno and Charles Eyriès had accomplished this major breakthrough in 1957 and developed a prototype prosthesis using electrical stimulation [1]. Credit is due to Blair Simmons and William House for being the first to spearhead a major research effort, against much opposition, to develop a practical cochlear prosthesis. At this dinner meeting, I was hugely impressed not only with what Blair Simmons had already achieved but also with his appreciation of Confucian philosophy: "Real knowledge is to know the extent of one's ignorance." The good doctor recognized that he did not have the expertise to perform the appropriate psychophysical experiments to evaluate the percepts provided by the implanted prosthesis. He had come to Jim Flanagan, who headed a team of leading speech and hearing researchers at Bell Laboratories, to perform these psychophysical evaluations. The meeting had a positive outcome, and once the necessary approvals were obtained from the powers that be, a joint research study was undertaken. The starship had sailed. Little did I know that I was to become its cabin boy.

The subject for the experimental investigations was a 60-year-old man who was both deaf and legally blind with severe tunnel vision. Since he was a disabled veteran, arrangements were made for him to be evaluated at the Department of Veterans Affairs (VA) medical center at Lyons, New Jersey, which was close to Bell Laboratories in Murray Hill. Because of his deafness, we were unable to communicate with him orally, and because of his tunnel vision, we were restricted to messages written in large block capitals on a huge sheet of white cardboard. His deafness had been acquired postlingually and his speech was reasonably good, so he could talk to us without difficulty. He was extremely pleasant and very cooperative.

The experiment was my first exposure to "real science," and it was a dramatic learning experience. I was going to work on an experiment with five of the world's leading hearing scientists at Bell Laboratories. The experimental results of this historic experiment have been published [2] but without any inkling of the excitement and emotional ups and downs experienced during the experiment. Two incidents are permanently ingrained in my memory. After a wealth of information on the pitch and loudness of the various electrical stimuli had been gathered, speech was presented as if it were just another abstract psychophysical signal. The subject responded that he heard someone talking. Silence descended like a bolt of lightening, sans

*_per ardua ad astra_: through adversity to the stars.

thunder. For five self-assured scientists who are allergic to silence to remain speechless for any length of time is very unusual, yet the silence persisted for what appeared to be an eternity as the next question for the subject was hastily written out in block capitals: WHAT DID THE PERSON SAY? (or words to that effect). After a long pause, the subject responded to the silent entourage that he did not know. It just sounded like speech. Instant elation transformed to instant deflation. We made several other attempts to present speech electrically, but the speechlike sounds that the subject heard were not intelligible.

The other incident is recalled with embarrassment. As the lowest member on the totem pole, I was given the task of keeping an eye on the subject as the others went off for lunch. It was an ideal time for me to get to know the subject. Although the method of communication was slow and laborious, I was able to learn something about him. He enjoyed being a subject and especially being able to hear sound once again, despite the fact that the sounds were highly distorted. He also revealed that it was the first time since becoming both deaf and blind that so many people had paid so much attention to him. Then it happened. Without warning, he stood up and announced that he was going to the toilet. This was an unplanned event with potentially disastrous consequences. I was alone with him. He was hardwired to a large rack of equipment. If he took a step forward, this heavy rack of equipment would be pulled down on top of him or, worse still, the connecting wires would be ripped out of his skull. I instinctively pushed him back into his seat and he grabbed me as he sat down. The next thing I knew, I was sitting on his lap. I did not know what to do. I thought desperately about how I could disconnect him from the equipment while at the same time getting him to sit still so that I could do it safely. Fortunately, the others returned at this moment. With great relief, I explained that he needed to respond to nature's call. The connecting wires were soon safely disconnected and he was able to get up and walk away from the equipment without mishap. Curiously, nobody asked me why I was sitting on his lap. They were too busy discussing the morning's data to notice anything unusual.

It was now time for my lunch break. I excused myself and went to the cafeteria. However, I was too upset by the near disaster to eat anything. The next day, I asked to be dropped from the experiment. So ended my first exposure to "real science."

The electrodes in this experiment were implanted in the modiolus portion of the auditory nerve. Unfortunately, the modiolus is not structured tonotopically, so inserting electrodes to stimulate prescribed frequency regions is very difficult. The cochlea, in contrast, has a tonotopic structure in that sensitivity to the frequency of stimulation varies monotonically with distance from the stapes. Thus, developing an auditory prosthesis for conveying complex spectrotemporal signals (e.g., speech) by means of electrodes inserted into the cochlea is a much simpler task. William House, ably supported by the fund-raising efforts of his brother Howard, embarked on this approach and achieved some measure of success with a single-channel cochlear implant.

The work on single-channel cochlear prostheses, however, soon met with substantial opposition. Many in the scientific community argued that a single channel of auditory stimulation was insufficient to convey a signal as complex as speech and that the same amount of information could be conveyed by means of a wearable tactile aid and without the need for invasive surgery. The opponents of cochlear prostheses, however, underestimated the importance of reconnecting a deafened person to the world of sound. Although a tactile aid can convey as many bits of information as a single-channel cochlear prosthesis, it cannot convey the subjective experience of hearing sound, which is of considerable importance for a deafened person.

Opposition to the implantation of single-channel cochlear prostheses soon grew into open hostility. The situation was not helped by the fact that early reports on the results of single-channel stimulation took the form of anecdotal observations rather than hypothesis-driven experimental studies. To make matters worse, claims were exaggerated in the lay press regarding the efficacy of these cochlear prostheses. Matters came to a head in 1974 when the Department of Health, Education, and Welfare was advised that "cochlear prostheses would empty the schools for the deaf." The Department was in the midst of a major cost-cutting effort and this claim, even if exaggerated, was too good not to be true. Pressure was exerted on the National Institutes of Health to look closer at the potential value of cochlear prostheses and, accordingly, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) called a high-level meeting of the major protagonists to discuss cochlear prostheses and make recommendations regarding future research.

The meeting took place on July 22 and 23, 1974. A Chinese curse states “May you live in interesting times,” and it was an interesting meeting. Not pleasant, but interesting. The following incident illustrates the depth of the deeply held feelings. It was the end of the first day and we were waiting in line for taxis to take us back to our hotel. It was a hot muggy summer day in Washington, it was rush hour, we were tired, and taxis were few and far between. The person at the head of the line was a strong proponent of cochlear prostheses, while the next two in line were strongly opposed to implanting “these gadgets.” A taxi arrived after a long wait and the head of the line kindly offered to share the cab with the next two in line. The response was prompt, curt, and negative. Another long wait followed in the Washingtonian summer heat before the next taxi arrived.

The meeting on the second day was surprisingly cordial. Perhaps the individuals involved had already vented their spleen and were now ready to talk turkey. The outcome of the meeting was a very helpful compromise. The attendees agreed that a detailed experimental evaluation would be performed on the 13 patients who had already been implanted with a cochlear prosthesis (all single-channel) and that a moratorium would be placed on further implantation for the time being. NINCDS then prepared a request for proposals (RFP) soliciting research applications for the evaluation of patients fitted with cochlear prostheses. The RFP was issued on March 24, 1975. The group headed by Robert Bilger and Owen Black at the University of Pittsburgh was awarded the research contract to implement the evaluation protocols. Because of the sensitive nature of the proposed experiments, NINCDS took the unusual step of appointing a team of consultants to serve as an oversight committee. I was a member of this interesting committee.

The investigations covered a broad range, including the otological, audiological, vestibular, and neurological status of the subjects; electroacoustic measurements of the devices; psychophysical evaluations; speech-recognition testing; postural stability; and subject acceptance of the prosthesis. Research is said to be the documentation of common sense, and almost all the results obtained in this major investigation were consistent with common sense [3]. However, one unexpected finding arose that uncommon sense would have predicted. The test battery did not include an evaluation of the subjects’ speech production with electrical stimulation, but several of the subjects were observed informally to show a noticeable improvement in speech production when the prosthesis was switched on. Previous research on speech production by deaf people has shown that a small amount of residual hearing is of great value in helping develop and maintain good speech production. Although the cochlear prostheses evaluated in this study provided only a limited amount of hearing, it was sufficient for improved speech production. In retrospect, not to have insisted on objective evaluations of speech production was an oversight of the oversight committee (*mea culpa*).

At this early stage, the primary focus in evaluating cochlear prostheses was on sound recognition. The cochlear prostheses evaluated in the Bilger-Black study provided a small but significant improvement in speech-reading ability, as well as limited recognition of environmental sounds. These improvements were similar to those previously demonstrated with tactile aids so that these findings did not allay the opposition to cochlear implantation. Although the Bilger-Black study did not include objective experimental evaluations of improved speech production, several subsequent studies documented the significant improvements in speech production obtained with cochlear prostheses. This was the first clinically significant evidence of the superiority of cochlear prostheses over tactile aids as an aid to speech communication. It was also the beginning of a trend in which the unique capabilities of cochlear prostheses were demonstrated unequivocally in well conceived objective experiments. Unfortunately, it was many years before cochlear prostheses earned a respectful place in the treatment of hearing loss and the unabated pressure on the pioneering researchers took its toll. In my last meeting with Blair Simmons, he revealed his bitterness toward what he referred to as the "tactile mafia" and their unrelenting opposition to his work.

It was the 10th International Congress on Acoustics in Sydney, Australia. I was one of the thousands of attendees who made their way down under for the occasion. While in Australia, I took the opportunity to visit Graeme Clark and his research group at the University of Melbourne. The distance from Sydney to Melbourne is not very long on the map of Australia, but it turned out to be quite a journey. Australians will also tell you that the distance between Melbourne and Sydney is much longer than that shown on any atlas and should not be measured in miles but in decades. On the surface, Melbourne is a placid place, seemingly several decades behind Sydney. The slow moving streetcars may create this illusion. Below the surface, however, things were moving at a rapid pace, especially with respect to the development of a practical cochlear prosthesis. The single-channel cochlear prosthesis developed by William House was an important step forward, but single-channel stimulation has inherent limitations and several research groups were actively working toward the development of a practical multichannel cochlear prosthesis. The members of the research team led by Graeme Clark were working toward this goal quietly, efficiently, and with little fanfare. A short note published a few years earlier indicated that they were close to solving two key problems: stimulating a large number of frequency regions in the cochlea and constraining the electrical field to a relatively narrow spatial region [4]. By 1980, they had implanted several patients and were achieving impressive results.

On the day I visited the University of Melbourne, they were evaluating one of their patients. Even though the patient had a classic corner audiogram, I was able to maintain a conversation with him in face-to-face communication. This was impressive. Even more impressive was his spontaneous observation that I had an accent, although he had no difficulty in understanding what I was saying. This stunned me, since many Americans with normal hearing have difficulty understanding my accent. Bear in mind that this was a face-to-face conversation and perhaps my lip movements were distinctly un-Australian. The team pointed out to me that although he was a good patient, he was not their best patient and that one of their more successful implantees was scheduled for the next day. I was invited to visit, which I did. This patient was not only able to maintain a face-to-face conversation without difficulty, but he was also able to understand bits and pieces of what I said without visual cues.

Before this visit, I had harbored doubts regarding the practicality of direct electrical stimulation. After the visit, I was convinced that cochlear prostheses would soon be a viable means of intervention, at least for profoundly deafened adults. As it turned out, cochlear prostheses have become a viable means of intervention for a much wider range of patients, including prelingually deaf children. The cochlear prosthesis developed by Graeme Clark and his research team was the first truly successful cochlear prosthesis and the first to be approved by the Food and Drug Administration for clinical use. For Graeme Clark and his colleagues, it was a journey from "down under" to "up on top."

The visit to Melbourne created a philosophical dilemma for me. My opinion of the clinical potential of direct electrical stimulation changed dramatically after meeting with two relatively successful implantees. I did not scrutinize objective data gathered in controlled experimental conditions. As a scientist, shouldn't I have waited for substantive experimental validation of what I saw on my visit before changing my mind?

A related challenge for scientists is that of experimental observations that defy common sense, although uncannily predicted by those with uncommon sense. The case in point is that of "star" performers. By the mid-1980s, more than a few implantees (several with single-channel prostheses) could understand conversational speech, including a few who could even communicate over the telephone without the aid of visual cues. No obvious scientific explanation existed for their remarkably good performance. Since very few implantees could perform this well at this early stage, they were referred to as stars. As one wag put it, "They understand speech the way humming birds fly. It cannot be done according to current scientific theory."

One of the most dramatic experiences in my professional life occurred when a group of star performers served as panelists at a scientific meeting. They each described their experiences with cochlear prostheses and answered questions from the audience. The questions were repeated by the moderator so as to provide visible speech-reading cues. The audience was clearly impressed with the exceptional speech-recognition abilities of these star performers. The most dramatic part of the meeting, however, occurred after the session had ended. The microphones were switched off and the audience had left when the panelists began conversing with one other. I was amazed at the spontaneity and liveliness of the conversations. Bearing in mind that only 1 or 2 years ago these stars could only communicate with sign language, this was truly remarkable. It gave new meaning to *per ardua ad astra* (pun intended).

Although multichannel stimulation had obvious theoretical advantages over single-channel stimulation and these advantages were supported by a growing body of experimental data, a significant number of researchers and clinicians still favored single-channel stimulation. They argued that a shorter, less invasive electrode can be used with a single-channel prosthesis and that, since there were already several star performers with single-channel prostheses, this form of stimulation should not be discounted. To resolve the controversy, researchers performed a randomized clinical trial to evaluate cochlear prostheses, both single-channel and multichannel. This major undertaking was jointly funded by the Cooperative Studies Program and the VA Rehabilitation Research and Development (RR&D) Service, Medical Research Service.

Three cochlear prostheses were evaluated: a single-channel prosthesis and two multichannel prostheses. Eighty patients at seven VA centers were implanted with one of these prostheses according to a randomized design. The patients were then evaluated over 2 years. In addition to the researchers and medical personnel who provided patient care, the study also included a team of statisticians from the Cooperative Studies Program Coordinating Center and a Data Monitoring Board, to which I was appointed.

Once again, participation in a major experiment involving cochlear prostheses was an interesting experience. In this case, the experience was both enjoyable and educational. One particularly interesting issue arose when one of the multichannel devices failed such that it functioned as a single-channel device. What do we do with the data for this particular instrument? Do we omit these data in determining the average scores for a multichannel device? Do we combine these data with the data for a single-channel device? The position taken by the professional statisticians was that this was not an experiment comparing single-channel and multichannel stimulation as such, but rather an evaluation of three specific clinical devices. If a specific instrument does not function properly, the data for that instrument should still be included in evaluating the device represented by that instrument. Reliability is an important consideration in evaluating a clinical device.

Every experiment involving human subjects needs to consider the possibility that one of the devices (or procedures) may be significantly poorer than the others being evaluated. This may not be known at the start of the experiment, but if it becomes evident during the experiment then, for ethical reasons, discontinuing the evaluation of the device that is significantly poorer is necessary. Evidence was mounting that one of the three devices in the clinical trial was significantly poorer than the other two. Since this was a double-blind study, none of us knew which device it was. A meeting of the Data Monitoring Board was called to decide whether to discontinue implanting the poorest of the three devices. This decision was going to be difficult, since the level of statistical significance was at a borderline level. We did not wish to withdraw a device prematurely, since it might be a very good device with its superior performance masked by random fluctuations, but if we waited and subsequently found out that we should have withdrawn the device earlier, the weight of the incorrect decision would have weighed heavily on our collective conscience. The burden was lifted from our shoulders when the manufacturer of the device in question withdrew its product before the meeting occurred. We then found out that it was the single-channel device.

The clinical trial established the superiority of multichannel stimulation, at least for the three devices that were evaluated in the trial. Multichannel stimulation is now the norm, although some limited applications for single-channel stimulation using a short electrode still exist. For a description of the clinical trial and its results, see Cohen et al. [5].

Research on cochlear prostheses has advanced at a rapid pace since these early pioneering efforts. Exciting new developments include bilateral electrical stimulation, bimodal (electrical and acoustical) stimulation, significant advances in electrode design, and new methods of signal processing that provide not only improved speech reception but also improved sound quality and the ability to hear and appreciate music. We are still in the midst of our journey, but the ride has become much smoother and the milestones are passing by at a much faster rate.

THE ARTICLES

The first entry (p. xviii) in this special issue is a personal recollection by a veteran, Mark Ross, who acquired a severe hearing loss while in the service. He was fitted with a hearing aid and participated in the aural rehabilitation program then being offered at military hospitals. After leaving the service, Mark became an audiologist specializing in auditory rehabilitation. He has since become an authority in the field. He has used a hearing aid for many years and was recently fitted with a cochlear prosthesis as his hearing deteriorated. His personal recollections of what it is like to use a hearing aid followed by the use of a cochlear prosthesis is illuminating. Since he is an expert in auditory rehabilitation and has also coped with a severe hearing loss for most of his adult life, his observations are particularly valuable. One seldom has an expert who is both a consumer and a provider. His familiarity with both sides of auditory rehabilitation provides him with unique insights that deserve special attention.

The first technical article by Graeme Clark (p. 651) is a personal account of his role in the development of cochlear prostheses and a view of the future. One hallmark of good science is to ask the right questions. Dr. Clark asked the right questions from the very beginning. The key problems he identified in 1969 (see quotation from his doctoral thesis on p. XXX) were addressed logically in the years that followed, resulting in his development of the first truly successful cochlear prosthesis. Two major advances that contributed to this success were the development of a flexible electrode that could stimulate as many as 22 frequency channels and a method of signal processing that reduced mutual interactions between frequency bands in the cochlea. Predicting the future is very difficult, and the accuracy of prediction cannot be evaluated until afterward, but given Dr. Clark's track record in asking, and solving, the right questions, his view of the future is likely to be remarkably accurate.

The second article by Wilson and Dorman (p. 695) provides an overview of contemporary cochlear implants from the designer's perspective. Anatomical and perceptual issues are discussed, as well as modern signal-processing strategies and how these strategies affect the perception of sound and speech in particular. Bearing in mind that the authors have made significant contributions in these areas, the material presented is insightful and provides a revealing view of the issues involved in developing a practical prosthesis. Their review of the strengths and limitations of present systems is also very helpful, as is their identification of problems to be addressed.

The third article by Rebscher et al. (p. 731) provides a similar *tour de force* of electrode design. The development of improved electrode arrays is crucial for further significant advances in cochlear prostheses. This research team has made major advances in this area and continues to do so. The article begins with a summary of the issues involved in electrode design, the key problems that need to be addressed, and their approach to solving these problems. The complexity of the problem and the difficulty of developing improved electrodes are evident from the data, and detailed illustrations are presented in the article that also illustrate the impressive progress being made.

The fourth article by Firszt et al. (p. 749) reviews the advantages of binaural hearing and, concomitantly, the disadvantages of monaural and asymmetrical hearing (one ear much more sensitive than the other). The advantages of binaural hearing can be provided to individuals with hearing losses in several ways. Binaural hearing aids work well for mild or moderate symmetrical hearing losses but not that well for severe losses or highly asymmetrical hearing losses. The use of bilateral stimulation is a promising new approach, and the findings reported in this article are extremely encouraging. These findings include results obtained with bilateral electrical stimulation for severe hearing losses in both ears and bimodal stimulation with a cochlear prosthesis in one ear and a hearing aid in the opposite ear for an asymmetrical hearing loss. This article is the last article (co)authored by the late Margaret Skinner and, as in all her previous work, is a valuable contribution to the field.

The fifth article by Turner et al. (p. 769) reports on developments in the emerging area of bimodal stimulation (electrical and acoustical). Bimodal stimulation can be either unilateral, with both electrical and acoustical stimulation in the same ear, or bilateral, with a cochlear prosthesis in one ear and a hearing aid in the other. Bimodal stimulation is particularly valuable for patients with severe high-frequency loss but relatively good residual hearing in the low frequencies. The two forms of stimulation complement each other in that electrical stimulation is more effective in the high frequencies, while acoustic amplification is more effective in the low frequencies. The authors of this article are pioneers in the development of a more general prosthesis combining electrical and acoustical stimulation in a single instrument. The experimental results reported in this article provide strong evidence in support of this innovative approach. Expressed simply, the whole (combined stimulation) is greater than the sum of its parts.

The sixth article by Drennan and Rubinstein (p. 779) addresses another area at the cutting edge, signal processing for music perception. The article explains why music perception is so poor in existing cochlear prostheses and reviews various approaches that have been used to improve music perception with electrical stimulation. A novel method of electrical stimulation is described that could improve music perception as well as the perception of other complex sounds. Preliminary results with this new approach are promising, and some listeners have described the ability to access music again. As noted earlier, the main focus of research has been on improving speech recognition, but other aspects of sound are important and should not be overlooked in the drive to develop improved cochlear prostheses. Music appreciation is one such consideration, and the work reported in this article is encouraging.

The VA RR&D Service played an important role in supporting research on cochlear prostheses at a time when conventional wisdom did not consider direct electrical stimulation of the auditory system a viable approach for an auditory prosthesis. The articles that follow serve as an impressive record of how far the field has advanced and the substantive benefits provided by modern cochlear prostheses to veterans and others with significant hearing loss. This special issue of the journal is a fitting tribute to the foresight of the VA RR&D Service in supporting research on cochlear prostheses from the very beginning.

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