



## Innovative Mini-Invasive Treatments with New Devices for Upper Respiratory Flogosis: Thinvasive Protocols with High Technology Balloons and Quantum Molecular Resonance

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### Abstract

Numerous new instruments have been introduced on the medical market in recent years: Latest generation hemodynamic balloons with shock wave emission; balloon scoring and drug releasing; third generation radio frequencies with regenerative action based on the theory of Quantum Molecular Resonance (QMR); kinetic-oscillatory stimulation balloon KOS (Kinetic Oscillating Stimulation). All these innovative tools; as we named Thinvasive DRB system; represent the basis for modern therapies capable to ensure good maintenance and improving the barrier mechanisms of the upper airways as a whole. In our review we describe these integrated approaches aim to prevent; for example; infections from viruses; bacteria or fungi; reduce the symptoms of rhinitis and sinusitis; and improve the performance of the organism and the quality of life.

**Keywords:** Balloon; Endoscopic sinus surgery; Eustachian tube; KOS; Obstructive sleep apnea; QMR; Rhinitis; Sinusitis; Turbinate

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### Introduction

The sharing of the most advanced aspects of scientific knowledge in the ENT field highlights the importance (especially in this period of viral pandemic) of the protection and study of the defense mechanisms of the airways and above all of their correct maintenance because numerous advances have been made in terms of advanced diagnostics and we too as a research group with the joint experience of the research groups of SIDERO onlus (Italian Society for the Diffusion of Endoscopy and Mini invasive Surgery); Order of Malta and CONI (Comitato Olimpico Nazionale Italiano).

Diseases of the upper respiratory tract are widespread in industrialized societies: It is estimated that in Italy there are more than 10 million adults affected and according to data transmitted by the WHO (World Health Organization); chronic respiratory diseases and respiratory tract infections are the cause in the world of 1,967,000 deaths every year. Furthermore; respiratory obstruction of the upper airways; especially if complicated with OSAS (Obstructive Sleep Apnea Syndrome) increases the risk of developing cardiovascular events (including hypertension; heart attack; stroke) by about 2 times and by about 5 times that of new onset of diabetes mellitus (if OSAS sufferers are also affected by metabolic syndrome); in fact the nasal and upper airway obstruction is able to reduce the concentration of oxygen in the noble tissues (insufficient oxygenation of the heart and brain) which will be in a continuous and wearying condition of fatigue with an increased risk of developing cardiovascular diseases (heart attack; hypertension) up to real cerebral ischemic events (stroke) [1,2].

Rhinitis in general and allergic rhinitis are the main cause of sickness absences; the fifth cause of antibiotic prescriptions and; in the case in which we force ourselves to work (presentism); they become the cause of contagion and a high percentage of dangerous and costly mistakes and accidents at work.

With my collaborators we have put in fact numerous personalized protocols of diagnostic procedures and above all therapeutic treatments that have been inspired by hemodynamic procedures; we therefore refer to balloon dilation treatments; always united by a red thread that

is an expression of our continuous pursuit of excellence in terms of minimally invasive treatments. A red thread that sees the complete respect of the respiratory mucous membranes; which are now a subject of extreme interest as we know that COVID-19 enters the body mainly through the nasal and nasopharyngeal mucous membranes.

The common thread of the respiratory tract; i.e. the Respiratory Syndrome (SR) as a whole; the global well-being of the human being recognizes the respiratory district in the upper and lower airways as a crucial point; respiration and oxygen intake are of primary importance due to their impact on the metabolism of the whole organism. As a constituent element of the health of the human body; reference is often made to the fuel; that is; to what we eat; but the oxidant of every metabolic reaction is precisely oxygen.

For our professional clinical attendance of a population of patients coming from CONI qualified environments from a sporting point of view with top athletes but also with all the common people who carry out amateur sports activities; but also the very common frequent flyers; those who take airplanes and trains on a frequent and regular basis; the actors; professional voice speakers; almost all the people who live a Western lifestyle: We could summarize that for each of them; good health and quality of life passes through a good functionality of the respiratory route. Any respiratory overload and alteration of the flow of breathing in the nose for the turbinates; paranasal sinuses; adenoids (in the child) at the level of the Eustachian tube; at the soft palate (night snoring and obstructive sleep apnea syndrome) all have a negative impact on cardiovascular system. For this reason; the importance and centrality of early diagnosis in the ENT (Ear Nose Throat) field once again underlines the importance of early prevention and therapy of inflammation and respiratory infections.

Respiratory diseases are the first cause of absence from work; a very important cause of presentism with presence in the workplace with reduced psycho-physical performance; a condition that determines a sharp increase in healthcare costs.

Fortunately; today we have many opportunities available to prevent and maintain the health of our airways in the best possible way; but it is necessary to implement an integrated; holistic; comprehensive approach for which the otolaryngologist represents the first diagnostic filter alongside the general practitioner next to the pediatrician; plan said next to the neurologist next to the cardiologist. It is necessary to consider how much damage from hypo-oxygenation and which negative consequences from hypomobility of the respiratory system have a negative impact on the state of heart health; negative consequences on blood pressure or worse cause a reduction in the performance and perfusion of the neurological and sensory noble district (sight; hearing). Therefore; the risks of failure to diagnose are above all a consequence of the lack of an all-encompassing and multidisciplinary culture in the early approach to the patient with respiratory deficit. Often it is not easy to reconnect how a small blow on the nose which is not given importance due to a trauma of many previous years; can lead to losing the attitude for sports or even for a simple healthy walk: Sedentary lifestyle appears; changes the style of life that becomes less active; a clouding of reaction times and psycho-physical performances appear; sleep alterations begin. Regarding sleep disorders and sleep apnea; today we unfortunately know that 22% of road accidents are due to sleep apnea syndrome which recognizes one of the main causes in the dysfunction of the airways. This alteration of nocturnal breathing also

determines negative cardiovascular consequences and we know that respiratory diseases with their negative implication in the reduction of perfusion of the neurological noble districts; together with diseases of the cardiovascular system are the main cause of death in the Western population [1-3].

For these reasons; respiratory disease today represents a problem to which the utmost attention should be paid in order to intercept its evolution in the earliest possible stages; also with an awareness of the general population with the help of self-assessment questionnaires; available free of charge on the website of the Sidero Scientific Society [www.sidero.it](http://www.sidero.it). Numerous new instruments have been introduced on the medical market in recent years: Latest generation hemodynamic balloons with shock wave emission; balloon scoring and drug release; third generation radio frequencies with regenerative action based on the theory of Quantum Molecular Resonance (QMR); kinetic-oscillatory stimulation balloon KOS (Kinetic Oscillating Stimulation). All these innovative tools represent the basis for modern therapies capable of ensuring good maintenance and improving the barrier mechanisms of the upper airways as a whole. These integrated approaches aim to prevent; for example; infections from viruses; bacteria or fungi; reduce the symptoms of rhinitis and sinusitis; and improve the performance of the organism [4-6].

The objective of balloon sinuplasty (the opening of sinus using balloon) is to clear the outflow of the sinus by dilating the ostium; allowing the remodeling of the area without any excision in the bones and the mucosa. These mini-invasive techniques using balloon from endovascular derivation; compared with traditional endoscopic nasal surgery; facilitate healing; allowing mucosa and cilia to regain their physiological function. Another advantage of this balloon procedures is that it has not to be necessarily performed in general anesthesia; allowing its use in office. Endoscopic sinus surgery and balloon sinus dilation share similar indications (with some advantage using balloon in term of safety; structural preservation and mucosal functional results); because both have the purpose to reach a better access to the sinus and a better ventilation; facilitating the return to a physiologic function and improving effects of maintenance medical therapies.

Quantum Molecular Resonance (QMR) radio-frequency produces waves with a specific form at high-frequencies (4 MHz to 64 MHz) and low intensity through electric fields (Telea Electronic Engineering; Sandrigo VI; Italy). QMR inferior and middle turbinoplasty with specific wands; in conjunction with medical therapy; improves the nasal flow; without any thermal mucosal damage; more effectively when compared with medical treatment alone; with synergistic and regenerative effects on mucosal health.

KOS treatment is administered using a minimally invasive system; consisting of a controller; connected to a single-use catheter (balloon) from Chordate Medical AB; Stockholm; Sweden. The balloon catheter; adequately lubricated with paraffin to facilitate its introduction; was inserted in both nasal cavities; without any anesthesia. For each nostril; the inserted catheter (balloon) was inflated and oscillated for 10 min at 68 Hz frequency; 65 mbar of average pressure and 100-mbar peak-peak pressure amplitude. KOS treatment activity consists in a cranial nerve stimulation method; conceived to treat non allergic rhinitis symptoms and with promising efficacy for acute migraine and other inflammatory disorders.

The warning symptoms not to be underestimated are many others compared to the classic stuffy nose and headache: Night snoring often mistakenly attributed to occasional excesses in food

or alcoholic beverages; and which is underestimated by simply inviting you to change the bedroom so as not to disturb the partner. Other symptoms of the ventilation deficit are disturbances in concentration; anxiety; morning fogging; perception of unrefreshing sleep; reduction of overall psychophysical efficiency; harmful effects on the Bronchopulmonary tract; many symptoms of this syndrome with a high social impact for which great efforts in recent years have also been made by our school to expand this wide angle from a small specialist window to arrive at an interdisciplinary approach.

Maintenance with a view to preventing the evolution and chronicization of these respiratory diseases focuses on the main sub-locations of the upper airways; which are the paranasal sinuses and turbinates. The nasal cavity and the turbinates today are often abused by the repetition of nasal swabs not always carried out correctly by the healthcare staff. Even the inflammation of adenoids and tonsils that must be remembered are a problem that does not exclusively concern children and the pediatric age; they can persist in adults and represent one of our lines of research in the perspective of organ preservation and selective remodeling with remediation limited to the diseased portion.

The social costs related to respiratory diseases are very high and increasing due to pollution and wrong lifestyles; their economic impact and quality of life is well known in the bibliography. Social costs and health are closely linked with a red thread and today also in Italy as in the rest of the world they are a problem that we must necessarily deal with if we want to guarantee a health system with access to treatment that is as universal; fair and ethical as possible.

Returning to the quality of life; a part of our scientific production has long been concerned with the impact on the quality of life; anxiety and depression; as secondary effects of any minimal alteration of respiratory function in maintaining the overall well-being of the person.

All these balloon dilation treatments for the nose; sinuses and Eustachian tube; all the regenerative and minimally invasive applications with Quantum Molecular Resonance constitute an ideal intermediate position between traditional surgery and medical therapy [6-9]. So our effort also with drug-eluting medicated balloons; sharp balloons; shock wave emitting balloons; all technologies that we learned from the enormous experience of hemodynamics and interventional radiology; has been to overcome the frontier point at which we have been dedicating for some years to rediscover a virtuous and synergistic relationship between the clinician and surgeon. These concepts and these technological-scientific acquisitions could define an otolaryngology 4.2 as we intend it in 2021 and it is important to use every opportunity to spread and share these concepts in a trans-disciplinary way; without leaving them limited to super-specialized professionals but with the aim of spreading this all-encompassing global concept. We want to promote the search for a multidisciplinary dialogue on all multimodal treatments between the various specialists of the respiratory tract (otolaryngologists; allergologists; bronchopneumologists; pediatricians; internists; geriatricians) and on technological advances as a guiding thread to make the most ethical medical choices possible and avoid complications. Intercepting diseases before they become chronic and saving even billions of Dollars or Euros in terms of social costs by using the new tools available today in our operating rooms and in our surgeries represents the challenge that passes through a necessary interdisciplinary dialogue. The use of molecular quantum resonance radiofrequency with regenerative

action on tissues; not demolishing but reparative; represents the tool that best interfaces between the different specialists in a functional way; as we define the treatments that have the purpose of restoring function without searching a geometric or anatomical result. Functional treatments according to Thinvasive protocols (as we named and registered all these new approaches) simplify the surgical procedure by minimizing trauma and the removal of structures; and thus reduce complications and clinical risks of damage to the barrier mechanisms of the upper airways; useful for protecting against infections and controlling hyper reactivity.

When the subtle mucosal and ultrastructural functional mechanisms were not fully known; it was preferred to remove osteo-cartilagineous portions of the internal nose and paranasal sinuses; thinking in good faith that improving by expanding the ventilatory space to the maximum possible would guarantee a better and lasting recovery from the disease. Today we understood that it was exactly the opposite; and even for extensive and massive pathologies; with the use of new technologies and devices according to the Thinvasive protocols; limited removals and minimal dilation enlargements are sufficient to restore the correct ventilation of the nasosinusal spaces; which only in doing so they recover their function in a progressive and definitive way.

Allergological diagnosis with the possibility of accurately identifying the pathogenesis of the disease and above all the availability of new drugs that integrate with cutting-edge biomedical technologies; first of all the new biological drugs for the control of respiratory immunophlogosis of polypoid rhinosinusitis [1,7].

With the integrated transdisciplinary approach we have understood how the simple resolution of the different and multiple obstructions of the upper airways in the different levels; when performed in a contextual way and when recognized the levels of the pathology with an advanced multispecialistic precision diagnostics; is able to heal the patient precisely because it minimizes the surgical trauma on each anatomo-functional respiratory sub-site; finding a balance point between overtreatment and under treatment.

An early and integrated approach to the patient with respiratory inflammation will allow us; for example; without demolitive interventions or excessive pharmacological loads; to have children who resume breathing well with the elimination of nocturnal snoring; and therefore are more lucid in the morning; ears that hear better and will not need to wear hearing aids; slowing the aging process.

What we have learned from hemodynamics; capable of treating from diabetic foot to cerebral ischemia passing from the coronary and carotid arteries by treating the polyvasculopathic patient simultaneously; also for the respiratory syndrome we perform an all-encompassing therapeutic action by minimizing the traumatic load having formulated a truly personalized diagnosis on the entire respiratory tree of our patient and able to restore well-being up to the lower passages of the bronchi and lungs.

The all-encompassing approach to respiratory health and the restoration of global respiratory well-being is today a goal that is easy to achieve; provided that new protocols are established with new high-tech devices and new medical therapies; partly personally described according to the Thinvasive method; in order to modify the natural history of rhinosinus disease and improve prognosis and quality of life. A symptom that is often underestimated and misunderstood in neurological differential diagnosis are rhinogenic headaches that

can be treated with the innovative Thinvasive protocols and allow people to travel freely and possibly eliminating the intake of high-impact drugs on the patient. The technology available today; also an expression of our research activity; allows the treatment of pathologies and related symptoms not yet fully identified from the pathogenetic point of view; for example; administering some drugs that can cross the brain barrier using the nasal corridor could give a new impulse to alternative pathways of absorption and pharmacokinetics. We believe it is important in this phase to be as open-minded as possible; to try to do an interdisciplinary brainstorming; to gather several different specialists within the great framework of respiratory diseases; the union is strength provided that the ENT surgeon uses a truly minimally invasive and conservative surgery. Naturally; turbinates represent the main target of the nasal inflammatory damage of rhinitis; a pathology that affects 35% of the population of industrialized environments. Inflamed turbinates hypertrophy and begin to secrete and cause many alterations in respiratory function and quality of life; since turbinate hypertrophy is so important for sleep; snoring and overall physical performance. The turbinates are the main target of our clinical and surgical attention and naturally the old amputation surgeries to remove the turbinates are to be abandoned and should no longer be performed. With the use of molecular quantum resonance a third generation radiofrequency with a unique action on tissue especially of children to interrupt the bonds between the molecules of the tissues without bringing heat; therefore with body temperature we are able with the use of dedicated handpieces to the different sub-sites; to have excellent functional results for the treatment of respiratory inflammation; in terms of reduction of the volume of hypertrophic turbinates; improvement of functionality with also reduction of allergy symptoms; nocturnal snoring and apneas; adenotonsillitis.

Snoring with obstructive sleep apnea syndrome has been a social emergency for many years (22% of road accidents are a direct consequence of them) unfortunately they are also capable of causing metabolic alterations; for example with diabetes mellitus and insulin resistance. There are therefore many interdisciplinary contact points in otolaryngology that deals with respiratory diseases in an updated way with the metabolic and general aspect of the organism and therefore once again we can implement metabolic and cardiovascular prevention in an interconnected way.

Today we have clinical diagnostic tools such as rhinomanometry; mucociliary function tests; oto-functional tests; very advanced polysomnography and capable of analyzing innovative parameters with the possibility of crossing the collected data; for which the otolaryngologist specialist is again a manager in cardiovascular and general diagnostic processes of the health of the patient; establishing a connection with extra respiratory symptoms; not always completely intuitive.

To help specialists for a easier and better spread of these protocols with balloons we named as Thinvasive DRB (Dilation Respiratory Balloon) System; a new mini-invasive endoscopic approach for the full recovery of Respiratory Wellbeing.

With this Thinvasive innovative functional mini-invasive surgery procedure developed and ratified according to our modern integrated research protocol; it is possible to improve and restore the correct performance and physiology of the respiratory system with great benefits for the whole organism (heart; metabolism; quality sleep; physical endurance; reduction of drug use and infections). The surgical approach Thinvasive DRB System is carried out rigorously

with a minimally invasive endoscopic technique (with the aid of QMR; high-tech balloon and its specific ENT introducers; KOS; medical therapy protocols) and represents the result of years of clinical studies in the continuous search for minimally invasive and maximally invasive techniques. Conservative; which recognize as a focal point the complete respect of the functionality of the delicate mucous membranes and structures of the upper airways (especially in children); with a simultaneous and contextual treatment of each of the pathological sub-sites; also integrated with personalized medical therapies. The Thinvasive surgical protocol; which many thousands of people have already used; is performed with a fast Day-Surgery treatment in complete safety for adults and children and is applicable after careful and advanced diagnostic investigations for all patients suffering from respiratory disorders or with the need to improve the ventilation of the ear; nose and throat districts.

In the specialist otolaryngology field; dealing daily with diseases capable of determining obstacles to the correct and full respiratory flow for the whole organism; we have framed the different clinical pictures so widespread as a consequence of Western lifestyles; responsible for the alteration of the physiology of upper airways; this complex of respiratory symptoms as a whole determine a pathology that is as disabling as it is widespread and too often underestimated and trivialized by both doctors and patients. Respiratory Syndrome (SR) describes a clinical condition that manifests itself through the contextual alteration; inflammation and/or obstruction at various levels of the respiratory tract; with the simultaneous presence of different pathological pictures that involve the individual districts of the respiratory tract with different severity; for patients who suffer chronic or recurrent symptoms of the Syndrome and refractory to medical therapy; these pathological pictures must be identified and resolved; all at the same time; with a single combined and all-encompassing action of Soft Surgery such as that of the Thinvasive DRB System. In fact; freeing just one or some of the obstructive respiratory sites does not succeed in determining stable healing; in a short time the positive effects of the individual interventions are nullified and there is the risk of having to subject the patient to a new and avoidable operative stress soon.

The early classification and treatment of the respiratory syndrome through the Thinvasive DRB System protocol allows to avoid the chronicization of the disease or the misunderstanding of even just one of the single components; because only by addressing it in all its phases and only using the most modern minimally invasive therapeutic solutions; is pharmacological and surgical; it will be possible to significantly reduce the pharmacological and surgical load itself and achieve a rapid; complete; definitive and practically painless restoration of the patient's respiratory well-being; both child and adult. Solving the obstruction localized in different locations with a single and single intervention leads to obtaining savings scales in terms of less biological suffering for the patient (one surgery; one anesthesia; one convalescence); in personal and social economic costs (fewer absences from work and school; earlier recovery to normal activities; lower spending on drugs; faster recovery of physical and mental efficiency; less use of health care facilities and nursing or home care by family members). Unfortunately; a respiratory awareness is still almost totally lacking; which would lead to forms of prevention; saving great suffering for patients and billions of Euros for the Health Service and society. Many prefer to tolerate even severe forms of these ailments due to the wrong choice of self-medication drugs often responsible for the chronicization of the Respiratory Syndrome; and



the significant traumatic impact that they still believe they have to endure for outdated and outdated surgical solutions; however still proposed in many centers.

The use of the Thinvasive DRB System surgical protocol with the most up-to-date minimally invasive technologies combined with the global approach to SR serves precisely to avoid this; identifying the minimum and sufficient balance point between over and under treatment by introducing an innovative concept of Minimal Effective Surgery that it will be tailored to the real clinical needs of each individual patient; and above all by maintaining the full and greatest possible respect for function as the first objective. Another consideration as a direct consequence of the global and multilevel mini-invasive functional approach that must guide every treatment for the recovery of respiratory well-being is the search for the restoration of the correct balance of the respiratory system altered by the disease; for example; partial or total removal of a turbinate completely unbalances the system to damage the paranasal sinuses and lower airways; as well as cutting and removing the adenoids and tonsils; exposes the strong risk of developing compensatory hypertrophy of other lymphatic tissues such as lingual base; and therefore causing in a very short time; as damage induced by the same medical act; a new pathological condition often worse than the previous one. Following this functional and personalized medicine reasoning; it appears evident that with the use of new technologies in a contextual way through the Thinvasive DRB System protocol; guided by an approach that tends to maximum respect for the function of the anatomical-functional segments treated; a multitude of "interventions" that must be adapted to the patient's singularity and uniqueness; unlike in the past in which there were a small number of interventions to which the patient had to adapt to whatever his respiratory pathology; very often without healing from the disease and let alone the symptoms; but suffering permanent damage. The direct consequence of this reasoning must lead to performing very conservative surgical treatments and with functional intent on the individual segments to be treated; as to restore the patient's respiratory well-being; by acting on the different pathological sub-sites; it is possible to divide the surgical action in a minimal way. On each of them obtaining a fully satisfactory overall result resulting from the sum of the beneficial effects applied at the same time; which taken individually will appear to have minimal traumatic impact for the patient.

Traditionally there have always been a certain limited number of upper airway surgeries to which the patient had to adapt to whatever pathology he was suffering from in order to find a solution to his problem; today; through the application of the Thinvasive DRB System; numerous interventions with reduced disability that can be associated with each other are finally available which must themselves adapt to the patient's pathology and anatomy which remain unique; with the main purpose of preserving or recovering respiratory function lost; this according to the modern Thinvasive protocol takes place completely independently of the search for anatomical perfection in terms of post-operative geometry and symmetry almost always in contrast with the functionality of the organ; which is a non-physiological condition and does not exist in nature.

The minimally invasive surgical techniques of the Thinvasive DRB System for the treatment of Respiratory Syndrome minimize pain; anesthesia; convalescence; eliminate bleeding and allow a rapid recovery of the patient to normal activities.

The Thinvasive DRB System minimally invasive surgery protocols

have proven to be able to avoid and reset these dangerous clinical conditions and prevent their aggravation and chronicization; with recovery of full Respiratory Wellbeing and improvement in the quality of life.

Some respiratory tract problems specifically concern athletes; and they are often the ones who neglect this important segment of the body; preferring almost exclusively cardiovascular; orthopedic or psychiatric checks.

**Our primary fuel is oxygen:** Putting less of it into our lungs is like putting less wind in the sails; less fuel in the engine; or using a gasoline with less octane. Respiratory problems such as stuffy nose, adenoids, hypertrophic turbinates, asthma; as well as the mere presence of mucus; reduce the flow of oxygen and therefore can reduce or impair a sporting performance; either simply physical or even unfortunately intellectual. A minimal reduction in respiratory flows can make the difference and compromise a race; slow down a decision especially when it comes to fractions of seconds; centimeters; reflexes; power and endurance. Why risk or worse give up when a good visit and the right therapy are enough to reset the entire respiratory system. Both professional and amateur sportsmen all have an enormous benefit from restoring the correct airflow both in terms of overall performance improvement and reduction of overload and cardiovascular risk; a risk that increases precisely in people who are out of breath or not properly oxygenated and trained.

Taking care of the respiratory tract allows anyone who leads a physically active life; both amateur and professional; to improve sports performance; temporally extend their career in the sport practiced; reduce recovery times between training sessions and reduce the risk of injuries.

In conclusion; especially in this era in which life is lengthening and the elderly population increases; each of us can benefit from proper maintenance of respiratory function and the resulting benefits are the best insurance for maintaining the good efficiency of the lung. Organism and the quality of life in full activity so important for the social repercussions and collective costs linked to disability; especially in old age.

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