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Review

Validation of a Novel User Interface and Calculation Method for Determining Nasal Resistance and Patency

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Abstract: Background: The Davidson Airway Function & Nasal Evaluation (DAFNE) Scoring System was developed as an intuitive and research-based scoring system that could be validated through beta testing and easily introduced to healthcare providers of several subspecialties who treat nasal obstruction and breathing disorders (MDs, PAs, PTs, APRNs, DDSs, SLPs, and DCs). This scoring system was shown to increase the knowledge of airway function, nasal measurement parameters, and identification of proper treatment options for sleep and breathing disorders. The basis for the DAFNE Score was developed from a systematic review of nasal measurement data. Methods: Electronic searches of PubMed, MEDLINE, EMBASE Cochrane Library, and Scopus of publications between 1988-2022 were used to identify studies validating nasal function measurement parameters to create the algorithm for the DAFNE Score. The systematic review was accomplished using the 2020 'Preferred Reporting Items for Systematic Reviews' (PRISMA) guidelines. Results: Twenty studies met the inclusion criteria for systematic review. Primary outcomes measurements demonstrated reliability, repeatability, and validity of the DAFNE measurement technologies, data, and output. Conclusions: The data analysis and systematic review uncovered a need and framework to develop and validate a web-based software algorithm for global access to improve the understanding of data interpretation of nasal measurements from three nasal measurement technologies. DAFNE Scoring System should be used as an adjunct tool in routine clinical practice and research to further understand the technology data output, treatment options and progress, and how to collaborate with other healthcare providers to improve patient outcomes.

Keywords: nasal function; validation; software; nasal resistance; rhinomanometry; acoustic rhinometry; peak nasal inspiratory flow meter; practice patterns; objective measurement outcomes; parameters

1. Introduction

In an era of medical innovation and technology, an estimated 20% of the global population are affected by nasal congestion and breathing disorders with many individuals undiagnosed or inadequately tested for nasal function and breathing. Nasal function affects overall health and contributes to pathophysiology of the respiratory system that extends into somatic functions. Access to interactive educational platforms as tools and guides for providers to improve their understanding of treatment options for such respiratory phenomena and the role of objective nasal measurements is not widely available and minimally applied [1,2].

Health information technology and digital health allows companies and providers to expand their reach in the healthcare market for analysis and personalization of patient care, specifically in the field of sleep disorders and airway measurement technology [1]. Access to digital tools measuring airway function and patency permits providers to holistically view patient health and opportunities to improve outcomes while enhancing efficiency in the plan of care [2]. Interactive computer programs with software functionalities

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and cloud-based informatics provide necessary access to research and develop algorithms guiding the healthcare provider (HCP) in understanding the particular data produced by a medical device. The data output and calculations within the software educate the HCP by guiding them through interpretations or analysis of a clinical test by providing certain types of limited clinical decision support [3]. Growth in digital health required clarity and changes by the U.S. Food and Drug Administration (FDA) and U.S. Department of Health and Human Services (HHS) [3]. They provided an amended legislative report on digital health in 2016 stating:

> *December 13, 2016 (Pub. L. 114-255), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain software functions from the definition of device under section 201(h) of the FD&C Act (21 U.S.C. 321(h)). These software functions are specified in section 520(o)(1) of the FD&C Act and the intended uses of such software functions can be summarize as follows: (1) administrative support of a health care facility; (2) maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; (3) serving as electronic patient records when not intended to interpret or analyze patient records; (4) transferring, storing, converting formats, or displaying data; or (5) unless interpreting or analyzing a clinical test or other device data, providing certain types of limited clinical decision support to a healthcare provider [3].*

The prevalence of nasal flow limitations and breathing disorders affects more than one billion people among the global population. The pathophysiological effect of dysfunctional breathing presents as a risk for obstructive sleep apnea and other disease comorbidities from birth through adulthood [4]. Additional risk factors include obesity and an aging population. The World Health Organization (WHO) reported the number of people affected by obesity doubled over the past five years further exacerbating the diagnosis of breathing disorders resulting in obstructive sleep apnea (OSA) [5].

Very few publications have proposed or defended the increasingly important need to measure nasal flow limitations in the clinical setting, yet more than two thousand publications have discussed nasal anatomy, nasal function, the nasal cycle, nasal resistance, and the objective measurement and testing options in research and clinical practice. Objective nasal measurements are an important part of clinical practice, but the technology and interpretation learning curve can take time and extensive training from the manufacturers. Current training and education on the data output has been minimal or self-taught, at best.

The current FDA approved objective diagnostic tests for nasal airway measurements are rhinomanometry, peak nasal inspiratory flow (PNIF), and acoustic rhinometry, but interpretive software or educational websites with software functionalities are lacking. Unlike Europe, countries in South Asia, the United Kingdom, and Australia, the allergists and ENT specialists in the United States infrequently use acoustic rhinometry and rhinomanometry and employ mostly for research trials [6]. Since 2017, and the upgrade in technology of the NR6 Rhinomanometer (GM Instruments, Ltd.) to 4-phase rhinomanometry, adoption of non-invasive, objective nasal measurements in the clinical workflow during pre, mid, and post treatment, is gaining recognition in dental and medical specialties. Because it functionally evaluates nasal aerodynamics and the transnasal pressure change biomarker, rhinomanometry may be preferable for evaluating nasal flow and function, while acoustic rhinometry is more helpful in locating the position and severity of nasal obstruction [7]. PNIF, like rhinomanometry and acoustic rhinometry, is a simple, dependable, reproducible, cost effective, widely available objective tool in measuring nasal patency, but lacks a pressure sensor to measure breathing across a pressure gradient [7].

Lacking a methodological approach to understanding airway measurement interpretation, DAFNE Scoring System was created. By identifying the problem, the DAFNE Score was written as an algorithm of computed device output and formulas to calculate, guide, and train the HCP in interpretation of nasal aerodynamic values for better breathing, collaboration, and patient outcomes. Once the algorithm was created, it was necessary to

validate that it correctly calculates answers for all readings across various patient populations.

The purpose of this systematic review is to identify and describe the data and research examining the three nasal measurement technologies from nasal measurements incorporating them into a software algorithm. To our knowledge, no such review has been conducted for the creation of an interactive, educational platform. Considering the clinical manifestations and consequences of breathing disorders, it would be beneficial to have an evidence-based user interface and calculation method for nasal resistance and patency. Furthermore, the platform of statistically tested research data could provide an entry into Artificial Intelligence (AI) and machine learning capabilities for airway measurements. The purpose of validation is to assure that this algorithm will work correctly and independently of the issues concerning the programming language. Once the validity of the method has been recognized and published, website interaction can be implemented.

2. Materials and Methods

A search strategy was developed to identify validated measurement parameters published for software and clinical algorithms to assist healthcare providers who use objective nasal measurements as a diagnostic tool for breathing disorders as a result of nasal obstruction. A three-domain nasal measurement-healthcare service as a patient model for validation was not discovered nor implemented for use in the market. The applicability of a new nasal measurement software algorithm to guide HCPs through the process of understanding the numerical testing output and interpretations formed the validation framework of this review.

2.1. Data Sources and Data Searches

Electronic searches of PubMed, MEDLINE, EMBASE, Cochrane Library, and Scopus were performed to identify publications between 1988-2022 validating nasal function and structure measurement parameters to develop an algorithm for the DAFNE Scoring System. A literature review was conducted and concluded in June 2022 using the Preferred Reporting Items for Systematic Reviews (PRISMA) guidelines [8]. A checklist for this review with search terms included and related to "nasal function," "validation," "nasal measurement software," "nasal resistance," "rhinomanometry," "acoustic rhinometry," "peak nasal inspiratory flow meter," "practice patterns," and "objective outcome measures." Synonyms and related terms were connected with the Boolean operator "OR" and combined with "AND." Medline (OVID) and EMBASE were searched for medical literature.

2.2. Selection of Studies

The authors selected titles and abstracts that discussed outcome variables that encompassed measurement consideration and sample descriptives such as gender, age, height, and technology used to measure nasal function and structure. Each method used to quantify the measurements were: nasal resistance measured in $Pa/cm^3/s$, nasal airflow measured in L/min, and cross-sectional nasal volume measured in cm^2. The full text of the each study relevant to the development of the DAFNE Score was reviewed for final inlcusion of the interface algorithm.

2.3. Data Extraction Data Extraction Process and Quality Assessment

Both authors independently reviewed the titles and abstracts that met the inclusion criteria qualified the relevant measurement data for rhinomanometry, peak nasal inspiratory flow meter, and acoustic rhinometer for data extraction.

2.4. Eligibility Criteria

Inclusion criteria consisted of human studies and systematic reviews that discussed: the normality criteria, normative parameters, diagnostic parameters, testing considerstions. Skeletal maturity related to nasal resistance, patient identification for collaberative care, and treatment parameters of various breathing disorder modalities was a consideration in the pediactric population when using 4-phase rhinomanometry, PNIF, and acoustic rhinometry. No case studies, meeting proceedings, abstracts, conference proceedings, abstracts, or studies using animals or the obsolete rhinomanometry technology were used prior to 2015. Performance bias showing inefficient use, faulty technique using the devices, or misinterpretation of the output data and parameters against the manufacturers' product manual were not included in this systematic review.

In assessing the risk bias of the included studies, the Cochrane Collaboration tool was used for specific domains to evaluate measurement properties in specified, relevant databases. The selection bias demonstrated ramdomness in sampling for each study outcome representative of a population. Performance bias detected adequate allocation of interventions that were open-labeled yet randomized lacking outcome report bias. The systematic review did not find other biases, incomplete data, missing results, or additional concerns. The only presumed performance bias would be the technique used to produce technical output data and interpretation of the data against the manufacturers' product information or FDA indications for use.

2.5. Analysis

The flow chart of the electronic database search and final selection of studies to be included in the systematic review and frequency of publication are outlined (Figure 1 & 2). Online searches resulted in 744 abstracts identified for the review, 3 duplicates were removed due to overlap of studies between the three technologies, and 523 articles were removed from screening for other reasons listed in the PRISMA flow chart. After identifying 523 articles, 218 were screened by title and asbtract. Of the 218 articles screened, 158 articles were removed for reasons such as non-English (n =7), the means of outcomes comparison were irrelevant to the algorithm (n = 109), and the research was utilized for the copyright and pending patent etc. (n =42) of the DAFNE Score. This resulted in a total of 60 studies assesed for eligibility, with 20 studies [9-28] to be included in this systematic review. Key details included studies for normative measurement values and treatment indications listed in Appendix A. Three studies [24-26] discussed the analysis of peak flow inspiratory flow limitations and parameters, 3 evaluated pediatric and adult acoustic sound measurements with rhinometry [14-16], and 14 evaluated rhinomanometry and mean resistance parameters as a diagnostic tool for various treatment options to improve nasal breathing, nasal function, sleep, and overall quality of life [9-14,17-23,27,28]. Figure 1 shows a majority of the articles reviewed were published between 2016 and 2022 after the validation of 4-phase rhinomanometry and its increased recognition as a standard of care for measuring nasal function in 2015 [29-30] .

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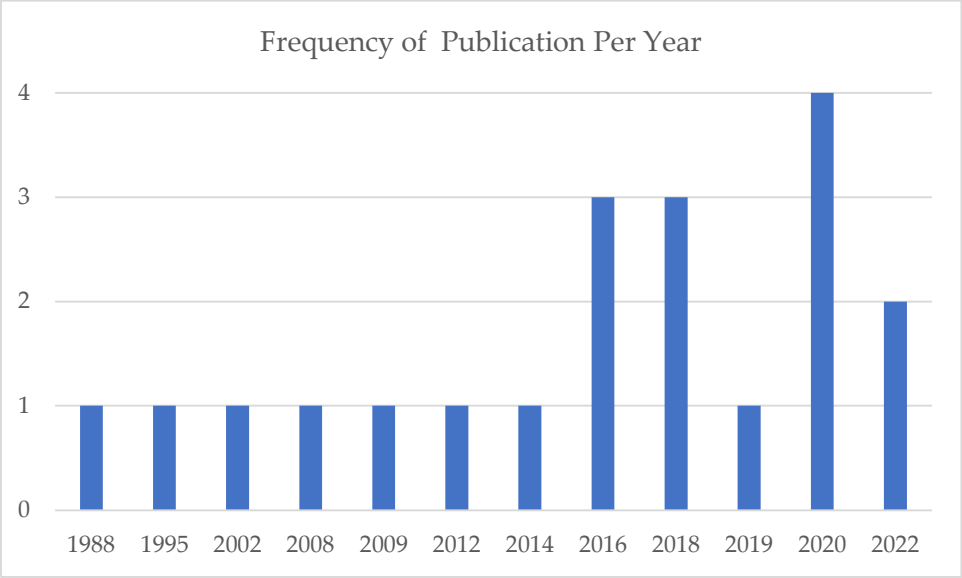

Figure 1. Frequency of publication per year.

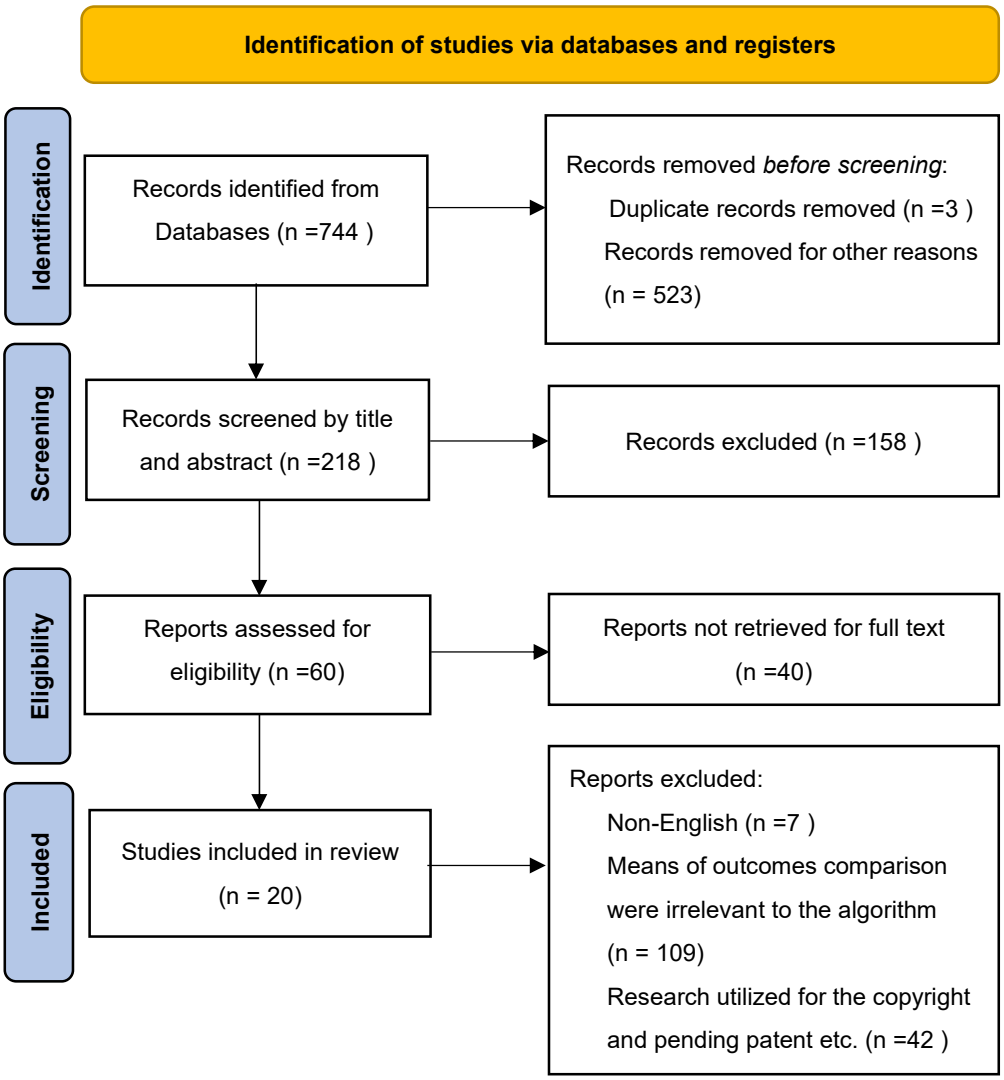

Figure 2. Reporting Items for the systematic review adapted to the 2020 Preferred Reporting Items for Systematic Reviews (PRISMA) guidelines.

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2.6. Characteristics of Included Studies

The outcome from the review of literature was to retrieve recent data within five years; however, the databases did not have enough data available for screening. The search extended back to 1988, 1995, and 2002 with one article retreived for each year. The lack of information in the 20th century was due to the genesis of the technoolgy, telemedicine, computerized software, and lack of human study paramters for clinical use until the late 2010's when rhinomanometry was reviewed with recommendations from the Standardization Committee in 2010 [29]. The advancement of the rhinomanometry technology began in 2015 with the systematic review of over 35,000 cases of rhinomanometry readings by Vogt et al. to conclude the new 4-phase rhinomanometry as clinically comparable and compatable to the subjective systems reported by patients on a questionnaire or verbally during the initial clinical assessment [30].

Regarding the journals publishing studies on the three technologies, there have been over 2000 publications over the past 30 years. However, the studies were related to the technologies as an outcome measurement tool, not the knowledge of the normative values and parameters for each device in order to assist the health care providers in a better understanding of what the data meant in detail, and interprofessional collaboration. Of the 744 articles identified, the relevant information needed to write the algorithm to support a validated algorithm was a sample of twenty articles.

The three technologies part of the review were PNIF, acoustic rhinometry, and rhinomanometry (Table 1.)

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Table 1. Comparison of nasal measurement tools[25].

	PNIF*	Rhinomanometry	Acoustic rhinometry
Definition	Device with a scale to measure nasal airflow and a nasal mask; manual, quick inspiration	Transducers that measure nasal airflow and differences in nasal pressure; nasal function	Ultrasounds; static measurement
Measurement	Nasal flows in liters per minute during maximal inspiration	Nasal resistance and conductance in Pascals, Broms, L/min of H_2O	Cross section and Volume between two points of the nasal cavity
Patient cooperation	Yes	Minimal for anterior; yes, posterior	Minimal
Reference values	Yes	Yes	Yes
Useful for nasal	Yes	Yes	Yes
Useful for surgical treatment evaluation	Yes	Yes	Yes
Strength	Portable; useful for home monitoring of patient's treatment; telemedicine	Still the 'golden standard' for measurement of nasal obstruction	Most used in children; guidelines for its use in nasal challenge test
Limitation	Alar collapse: not useful when nose totally blocked	Cost of equipment	Cost of equipment

*PNIF peak nasal inspiratory flow

2.7. Beta-Testing Approach

To ensure efficiency and product quality, a series of steps were used in the two-phase project. Several versions of the DAFNE Scoring System were conducted in the two-phase project to assess the calculations, organization, and the functionality of the algorithmic platform. In Phase 1, a systemic review of literature was conducted to obtain the normative values and treatment options based on the tested values. The values were used in the development of an algorithm as a decision making framework for breathing disorders. The creation of the data and algorithms are the first steps in machine learning and artificial intelligence with airway measurement tools. The beta testing involved a group of five physicians who agreed to serve as reviewers of the scoring system, and how well they were able to follow the methods that drove therapuetic improvement. After the testing, open ended comments and notes were reviewed for improvements. Collectively,

we were able to establish the validation and functionality of the scoring system to leverage the technologies in clinical practice.

2.8. Strengths and Limitations

The strength of the systematic review and validation of the DAFNE Scoring System show detailed multiple methods for gathering data on the normative values and testing parameters. We were able to provide enough information to explain the complex issues and validate the algorithm of the DAFNE Score without revealing too much proprietary information in developing the alogrithm for the web-based software. The number of studies used to research and write the algorithm allowed us to answer the how and why it should be implemented as a part of standard of care to further educate healthcare providers on the output data and measurementsof the technology.

While using the PRISMA methodology by identifying as many eligible studies as possible, with a clearly defined objective, the amount of related secondary data was either not available, accessible, or relevant in writing the algorithm. Many of the studies did not possess a clear knowledge of the technology, or the context of the published study was difficult to understand. The analysis of the data was time consuming and much more difficult to analyze as asepects of it did not fit into standardized categories such as the particular device and the normative values of the data output.

3. Results

3.1. Validation of Web-based Software

In this systematic review of literature to create and validate the DAFNE Scoring System, 744 articles were identified which resulted in 3% for review. The 3% inclusion of articles consisted of twenty with distinctive parametric information for each device. The PNIF had three studies to discuss the normative values in adults and children, and infants. Three articles for acoustic rhinometry discussed the normative values for adults and the impact nasal disease has on the mean cross-sectional area (MCA) and nasal volume from the anterior to posterior of the nasal passages. Of the twenty studies, fourteen emphasized the many aspects of rhinomanometry as it is the more advanced technology able to detect numerous problems with important measurements relating to breathing and body function, specifically nasal breathing.

Throughout the review of the literature, we were able to identify key parameters and normative values to enter into the algorithm of the DAFNE Scoring System. Furthermore, we were able to design an educational tool to assist health care providers around the globe on the designated values and parameters with decongestion, skeletal formation, nasal cycling, and suggestions for collaboration among other healthcare professionals. The main resistance values, nasal cycling, the mucosal membrane component, and rhinomanometric readings are necessary for understanding nasal airflow. Additional measurements for location of the obstruction and severity, conducted by acoustic rhinometry, allow the health care provider to locate the area of obstruction.

3.2. Literature Data

The literature showed a clear correlation between the distribution of apnea and hypopnea indices, nasal resistance, and symptoms at presentation among adults and children with sleep related disorders and breathing disorders, specifically in children with adenotonsillar hypertrophy [19, 23]. The association of skeletal growth and development were found to play a significant role in snoring and OSA compared to healthy children [23]. Novel approaches in the diagnosis of sleep and breathing disorders in adults and children presented a sensitivity and specificity as high as 96% [20]. This translates the device testing and data output as clinically comparable and compatible to the outcome of a diagnosis from a sleep study or the development of a diagnosis OSA prior to the initiation of a sleep

study [11, 12, 18, 20, 21, and 23]. The benefit of the device data proposes obtaining a baseline test of nasal resistance when a sleep study may not be an option or as an adjunct to the sleep study for comparative reasons pre, mid, and post treatment.

Early theories show how craniofacial development is based on the belief muscular and skeletal growth originates intrinsically from the effects of increased nasal resistance and decreased nasal airflow [19, 31, 32, and 33]. The correction of any specific skeletal anomaly or deficiency can improve breathing disorders, awake or at sleep, but the objective measurement is the key guide to understanding the severity of the nasal restriction, as well as the plan of treatment based on the normative values and results from the test. The association between nasal resistance, facial morphology, and breathing disorders is well documented amongst all populations from children to adults [31, 32, and 35]. These add comorbidities that result not only in sleep disordered breathing, but obstructive sleep apnea. Furthermore, the varying degrees of collapsibility in the pharyngeal airway are dictated by the pressure-flow relationship beginning in the nasal passages, not structure as previously thought. It is further noted that in a growing child, abnormal nasal resistance, or high resistance, may affect the mandibular and maxillary development specifically during pubescent years. There were ten of the 14 articles discussing these common structural issues measured with rhinomanometry.

The effects of mouth breathing propagate abnormal tongue position and altered oral facial muscular development and tone. The data showed laminar flow on inspiration is approximately 2 seconds and turbulent flow on expiration is approximately 3 seconds. Greater than three seconds on expiration will result in mouth breathing. Throughout the systematic review, we were able to find specific values inherent to the findings that supported the algorithm in the DAFNE Scoring System. As recent as 2020, the impact of nasal resistance and the distribution of apneas and hypopneas and obstructive sleep apnea have been noted where the genesis has been nasal resistance [21]. This finding may catapult the redirection of biometrics used in diagnosing OSA and other breathing disorders, although the pattern of recognized behavior in the sleep testing industry over the past fifty years will not be bi-directional in acceptance among medical societies. This calls for additional research to set the benchmark for new values considered in the progression of airway disease.

3.3. Ethnicity, Gender, and Age

In 1994, Jones et al found the correlation coefficients between cephalometric development and rhinomanometric measurements to be statistically significant specifically when measuring mandibular prognathism that also correlated to intranasal pressures and mean resistance [34]. These findings were between two racial groups that further discuss the unique differences among racial entities and ethnicities and the variations of head posture dictating treatment plans [33]. To address cephalometric changes in pediatrics among racial groups, Juliet et al. concluded the lower age limit for testing rhinomanometry at five years old with the reference pressures with the most appropriate pressures at 75 and 100 Pascals [35]. In addition to age and ethnicity, the data showed differences in the measurement output for all three-measurement devices among gender, specifically nasal volume and mean cross-sectional area at the three measurement points in a congested or non-congested state [11, 14, 18, 24, 26].

3.4. Indications, Treatment Modalities, and Outcomes

For more than 50 years, the treatments for breathing disorders and OSA have shown a relationship between nasal resistance, posture, and other potential factors that influence the changes in transnasal pressures against a specific pressure gradient, but do not discuss patient identification [20]. In 2020, Hsu et al. found nasal resistance in a supine position at 150 Pascals was able to provide information on the optimal PAP pressure required for tolerance [28]. Furthermore, additional studies concluded rhinomanometry as a valuable part of the treatment algorithm in OSA patients for optimal CPAP titration, specifically in the

mean resistance that indicates patient selection and tolerability of CPAP [12, 18, 21, and 28].

The review found studies discussing maxillary expansion as a primary treatment option to improve nasal breathing and target nasal resistance. The conclusions found positive aspects and improvement in nasal breathing from maxillary expansion, and oral appliances [20].

Various surgical interventions were mentioned in the literature of the systematic review and found the anatomical expansion of the nasal floor reduced nasal airflow velocity and a downstream reduction of the negative pressure in the pharyngeal area, which proportionately affects the collapsibility in obstructive sleep apnea [21, 22, and 30]. It was also discovered that the AHI correlates well with nasal flow and velocity reductions [22, 36].

3.5. Measurement Values of Rhinomanometry, Acoustic Rhinometry, and Peak Nasal Inspiratory Flow Meter (PNIF)

In the most basic form, DAFNE Scoring System evaluates the maximum mean testing score for each instrument and describes how to process the score into the treatment care plan. This was conducted through data analytics by establishing current researched normal measurement values and parameters for each technology as part of the algorithm [9-28]. We found consistency among the measurement variables discussing the conclusive amount of decrease in nasal pressures, increase in cross-sectional measurements, increase in nasal volume, and increases in inspiration measured in liters per minute among gender differences, age, and height used in the context of the scoring platform [10,11,14-16,24-26,34]. The validated measurements and biomarkers guided the formulation of an algorithm for DAFNE Scoring System from the login page, to entering the measurement value, to understanding the data to suggestions for interprofessional collaborative care. Through a multicenter beta test, the validity and functionality of the scoring system was demonstrated and proven for future AI and machine learning for therapy predictability and outcomes.

3.6. Algorithm Development

The concept of computing airway measurements was based on sustained data used to detect changes over time that can only rely on research and experience. The predicted research values of the DAFNE algorithm dictated the therapeutic options and interprofessional collaboration posed to solve complex airway and breathing problems. The platform language answered internal questions with mathematic and airway measurement input and logic that determined the output from the nominal entry. The combined algorithm model was able to analyze the measurements that with a global health approach will enhance the application of AI in airway measurement technology. After the algorithm is used over time, data collection will find correlations leading to improved care of identified normative values through coding instructions versus expert systems when creating prediction models determining what treatment protocols will work.

The model was created using 73 measurement data set parameters reported from previous research. It started with initializing the scoring system by entering a tested measurement with evaluation. If the values were within normal limits, no other selections or data was needed, and the criteria was stopped. If the values were abnormal, treatment modalities and times series information was entered for analysis and prompted for additional testing with interprofessional collaboration.

As with any innovative technology, there is a learning curve. Part of the learning curve can take months, or even years. It is our expectation that the development of the researched based DAFNE Scoring System will expedite the learning curve of understanding of objective, non- invasive objective airway measurements when dictating treatment and collaboration among medical professionals based on the validation system variables and scores.

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4. Discussion

Efficiency of the physiology and pathophysiology of respiratory and nasal function has become a topic of importance in the medical and dental communities. The quantifiable, objective measurement data has been delivered to the forefront of the conversation through clinical practice, research, and societal panel discussions. An identifiable need for training and guidance to better understand nasal function data output has been uncovered yet absent in the marketplace. Feeling intimidated by the technology and data output, many practitioners do not perform the non-invasive objective tests. The data output has been evaluated and shown which medical modalities are approached at different measurement levels. Within the new era of IA and machine learning capabilities of airway measurements, the DAFNE Scoring System answers the unmet need.

The main purpose of this contribution is to identify and describe a way to improve the evaluation of normative values tested from various airway measurement devices through an algorithmic scoring system that evolves into AI. The scoring system meets an unmet need in an algorithm software publication for education and machine learning capabilities for airway measurements from previous validated output data. Due to the lack of an algorithm publication and an increased use of the airway measurement technology, the scoring system was created in order to improve implementation with the data output. Validation of any web-based software platform must answer the simple question of "Are we building the right technology at the right time for the right audience to better manage patient care?" Will this give them a better clinical understanding of a particular technology, the value of the data output, and how to incorporate it into their workflow?

Healthcare decision makers in search of reliable information that compares health interventions increasingly turn to systematic reviews for the best summary of the evidence. Systematic reviews identify, select, assess, and interpret the findings of similar but separate studies, and can help clarify what is known and not known about the potential benefits and harms of drugs, devices, and other healthcare services. Systematic reviews can be helpful for clinicians who want to integrate research findings into their daily practices, for patients to make well-informed choices about their own care, for professional medical societies and other organizations that develop clinical practice guidelines.

This first of its kind systematic review for a web-based companion software conducted over five years found statistically significant outcomes in research measured to decrease nasal resistance and increase nasal airflow, both with and without nasal decongestant, surgeries, and expansion. Ren et al [9] explains how the reference values are useful in choosing and assessing a therapeutic intervention for nasal congestion or OSA, and Merkel et al. [13] explained the normative values and parameters in nasal disease improvement. The previous research reviewed and tested the effects of maxillary expansion and the role it plays in nasal function measurements, too. The tested and retested parameters are the foundation of the algorithm for DAFNE which further validate the existence of the platform for clinical care and education. The scoring system was specifically developed to accommodate the demands of telemedicine, telehealth, digital, electronic healthcare platforms, and educational needs for objective airway measurements requested at an international level. HCPs continuously use data-enabled infrastructures to support policy and planning, public health, and personalization of care.

The ease of use and the multiple access portals from a computer, notepad, or cell phone, allow HCPs to enter testing data after accepting the terms and conditions of the platform. The interface will direct the user to login with a username and password. They will tap on the technology tab, enter the population category, enter their mean resistance values, flow measurements in L/min, or cross-sectional values. The calculation or algorithm, based on clinical research and studies, will lead them to understand what that value means and what the next steps would be in order to help the patient breathe better. As part of the user agreement, it is noted that unidentifiable individual patient data protected under HIPAA will be accessible for larger research projects. The DAFNE Scoring System demonstrated the capabilities as a large data portal for further research in technology data

and patient outcomes to discuss results and how they can be interpreted from the perspective of previous studies and of the working hypotheses. The findings and their implications should be discussed in the broadest context possible. Future research directions may also be highlighted.

5. Conclusions

The diverse scope of digital health platforms includes mobile health (mHealth), health information technology (IT), wearable devices, telehealth, and telemedicine. From mobile medical apps and software that support the clinical decisions healthcare providers make on a daily basis to artificial intelligence, machine learning capabilities, and learning different technologies and devices, digital technology is driving a new revolution in the approach to pathophysiological health and healthcare delivery. Digital health tools have the vast potential to improve our ability to accurately diagnose and treat disease to further enhance the therapeutics choice and outcome of healthcare.

Digital health technologies use web-based software and computing platforms and connectivity for healthcare that span a wide range of uses, from applications in wellness to applications from medical device output. The data analysis and review of literature uncovered a framework to develop a software algorithm to improve AI in airway measurements and the understanding of data interpretation of nasal measurements from three nasal measurement technologies. Based on statistically significant outcome data, this review suggests that the DAFNE Scoring System is valid and can be used in the office or with a telemedicine delivery platform. Additionally, DAFNE is the first of its kind web-based, companion platform for diagnosing breathing disorders based on researched parameters, which show identification of appropriate treatments. With a simplistic user interactive program providing software capabilities for rhinomanometry, peak nasal inspiratory flow meter, and acoustic rhinometry, the HCP can learn the interpretation values and how best direct their treatment plan. The DAFNE Scoring System successfully integrated the reliability and repeatable research data for each technology into an algorithmic infrastructure to support HCPSs across the globe. Several beta-tested cases found that the software platform satisfied the functional requirements for launch to market.

DAFNE Scoring System and the developed algorithm is a validated web-based software companion platform to guide a healthcare practitioner who measures nasal obstruction and uses objective, non- invasive assessment tools in their approach to diagnosis airway and breathing disorders. DAFNE may be a valid platform, which has global access and can be routinely used in clinical practice or research to further collaborate with other healthcare providers and improve patient outcomes with the proper treatment plans. As clinical and research data improves, current measurement standards are refined, and new innovation becomes available, the algorithm measurement parameters in the software functions will be amended into a next version.

6. Patents

All aspects of the DAFNE Score and DAFNE Scoring System reported in this manuscript are proprietary, copyrighted, and patent pending works.

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Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable. This study protocol did not require a review by an Institutional Review Board (IRB) because the study did not involve human subjects. The unit of analyses were data from published articles and did not meet the definition of human subjects.

Informed Consent Statement: This study protocol did not require a review by an Institutional Review Board (IRB) because the study did not involve human subjects. The unit of analyses were articles from databases.

Data Availability Statement: The databases generated during or analyzed during the study are available from the corresponding author upon reasonable request.

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Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

Systemic Review of Articles to Validate the DAFNE Scoring System

Publication	Year	Population	Conclusions
Ren et al.[9]	2018	704	Reference values may be useful in evaluating nasal function and choosing and assessing efficacy of therapy for nasal congestion
Gammert et al.[10]	1988	46	Rhinomanometry is repeatable. Designated values for upper and lower values with decongestion
Janosević et al. [11]	2009	108	Information on total nasal resistance normal values in healthy adult population important for computerized rhinomanometry
Inoue et al.[12]	2019	711	Nasal disease and nasal parameters are key factors for early CPAP therapy
Merkle et al.[13]	2014	38	Normative values for adults
Krzych-Fałta et al.[14]	2022	583	Acoustic rhinometry parameters depending on age and sex-component of standardization in nasal provocation test
Laine-Alava et al.[15]	2018		Guideline Values for Minimum Nasal Cross-Sectional Area in Children
Strasszek et al.[16]	2008	256	Presented material will facilitate the interpretation and evaluation of future and present epidemiologic studies based on AR in children.
Calvo-Henriques et al.[17]	2020	257	Impact of maxillary expansion on nasal breathing and resistance in adults
Hueto et al[18].	2016	38	Relationship between nasal resistance and continuous positive airway pressure
Laine-Alava et al.[19]	2016	115	Upper airway resistance during growth in children
Calvo-Henriques et al.[20]	2022	291	Recumbent position affects nasal resistance
Hoel et al.[21]	2020	126	Impact of nasal resistance and the distribution of apneas and hypopneas in OSA
Yoon et al.[22]	2018	20	Expansion of the nasal floor is associated with reducing air flow velocity and OSA
Rizzi et al.[23]	2002	73	Nasal resistance is useful in identifying OSA in children
Ottaviano et al.[24]	2012	109	Peak nasal values in adults
Ottaviano wt al.[25]	2016	-	Review of nasal measurements
Prescott et al.[26]	1995	102	Peak nasal values in children infant to 8 years old
Calvo-Henriquez et al.[27]	2020	301	The role of pediatric maxillary expansion on nasal breathing in children
Hsu et al.[28]	2020	43	Rhinomanometry predicting CPAP failure

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