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Development and validation of the Sinonasal Endoscopic Score (SiNES) for chronic rhinosinusitis

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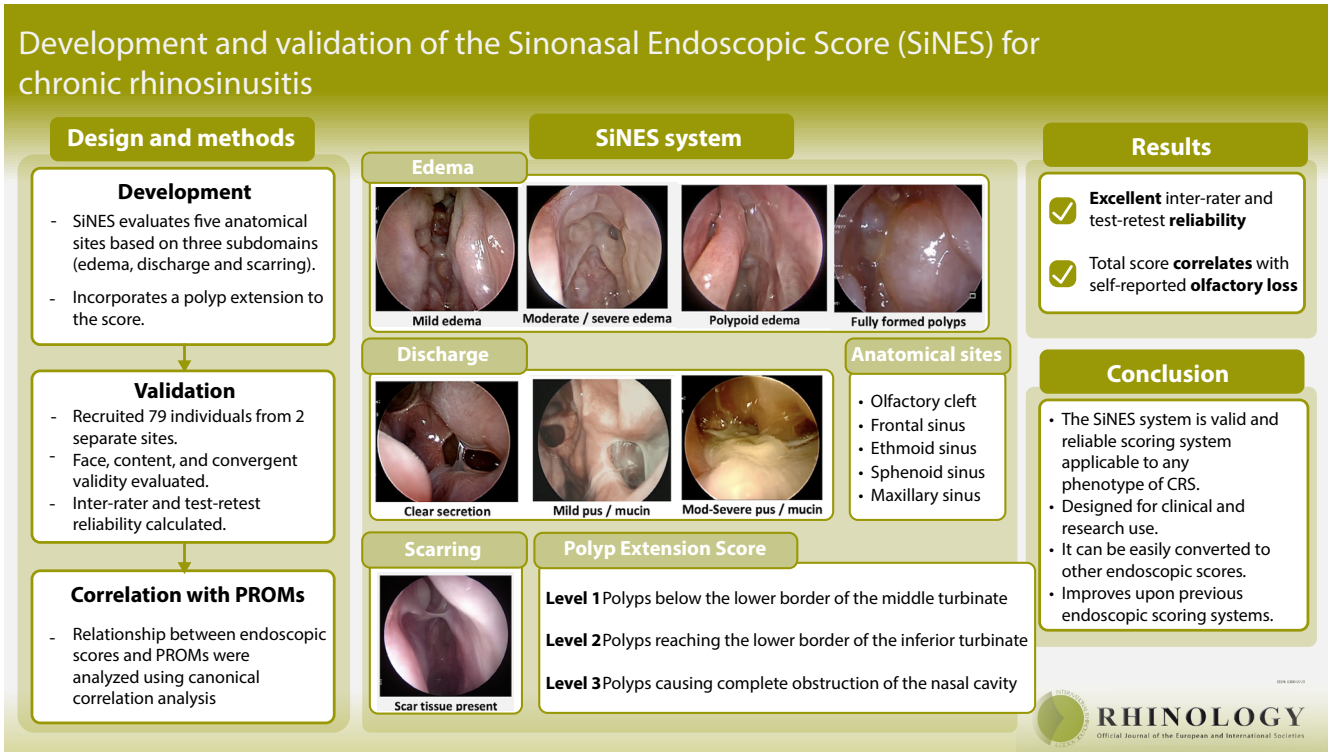

Abstract

Background: Although there are several endoscopic grading systems for chronic rhinosinusitis (CRS), they are limited in their range and applicability. We developed a SiNonasal Endoscopic Score (SiNES) that builds upon the strengths of previous systems while addressing their limitations.

Methods: The SiNES system was developed by consensus after multiple rounds of guided discussions. Face, content, and convergent validity were investigated. It was validated using an independent sample of 79 CRS individuals from two referral centres from September 2021 to February 2022. Each patient underwent a sinonasal endoscopy and filled PROM questionnaires. Three independent rhinologists graded endoscopic videos using the SiNES and modified Lund-Kennedy (MLK) scores. Inter-rater and test-retest reliability were assessed via the intraclass correlation coefficient (ICC). SiNES and MLK scores were correlated with PROMs using a Spearman correlation and canonical correlation analysis (CCA).

Results: The SiNES system evaluates five anatomical spaces regarding edema, discharge, and scarring. Face, content, and convergent validity were deemed satisfactory by the study authors and an independent panel of Otolaryngologists. Inter-rater reliability was excellent for the SiNES and good for the MLK score. Test-retest reliability was excellent for both systems. Total SiNES was correlated with self-reported smell loss.

Conclusions: The SiNES system is an accurate and reliable grading framework applicable to all CRS subtypes. It can be utilized in clinical and research settings and improves upon previously published systems.

Key words: chronic rhinosinusitis, nasal polyps, paranasal sinuses, quality of life, rhinosinusitis

Introduction

Endoscopic visualization of the sinonasal anatomy is the primary strategy for monitoring disease state in patients with chronic rhinosinusitis (CRS). Throughout the years, several endoscopic grading systems have been developed including the modified Lund Kennedy (MLK) [1], POSE [2], Discharge, Inflammation and Polyps (DIP) [3], and multiple versions of the nasal polyps score (NPS) [4–6]. Among them, the MLK and NPS are particularly popular among clinicians and researchers due to their ease of use and high reliability [1,7]. Both scores are frequently used as outcome measures in randomized controlled trials [8–11] and serve as objective estimates of the inflammatory load present in CRS.

Despite their strengths, the MLK and NPS have important limitations. First, both systems give an average score without offering details on the state of individual sinuses or important anatomical sites such as the olfactory cleft (OC). Thus, it impossible to differentiate cases involving the entire nasal cavity from those limited to a single anatomical site using these scores alone. Second, they have a limited range of values, which translates into large ceiling and floor effects [12]. For example, patients with normal sinuses will have the same NPS as those with diffuse polypoid edema due to the absence of fully formed polyps. Similarly, individuals with mild purulent discharge in a single sinus have the same score as those with severe and diffuse eosinophilic mucin. In the clinical setting, these issues are solved by explicitly writing the endoscopic findings – which defeats the purpose of having an endoscopic score in the first place – however, these issues have dangerous implications in clinical research since they can lead to measurement error and inaccurate estimations of a given treatment's effect size.

There is a need for a better endoscopic score that accurately reflects the sinonasal disease burden and is easily applicable in the clinical and research settings. Thus, the objective of this study is to design and validate a SinoNasal Endoscopic Score (SiNES) that builds upon the strengths of available endoscopic systems while directly addressing their limitations.

Materials and methods

Creation of the instrument

The SiNES system was developed through repeated discussions between a group of tertiary-care rhinologists at two international sites (Vancouver, Canada and Riyadh, Saudi Arabia). After a thorough literature review, we decided to use the Phillpot-Javer endoscopic scoring system for Allergic Fungal Rhinosinusitis [13] as a starting template since it grades each anatomical site independently. We then modified the score by agreeing on the most relevant subdomains and anatomical sites to be evaluated and determining the number of categories/points to be awarded to each subdomain. Polyp extension was given the highest weight in the overall score, followed by the degree of edema and discharge based on the correlation between these subdomains and quality of life scores [14]. We developed a pilot version of the SiNES system, tested it on ten sinonasal endoscopy videos, and then underwent a second round of guided discussions focused on the score's content validity. A final version of the SiNES system was agreed upon by consensus.

Instrument scoring

The SiNES system evaluates each individual anatomical space (i.e., OC, maxillary, ethmoid, sphenoid and frontal) regarding three subdomains: edema, discharge, and scaring (Figure 1). The edema subdomain ranges from 0 (no edema) to 4 (fully formed polyps), eliminating the need for a polyp specific subdomain. Similarly, the discharge subdomain is categorized as 0 (no discharge), 1 (clear secretion), 2 (mild purulent discharge or mucin), and 3 (moderate-severe purulence or mucin). Having categories for mild vs moderate-severe purulent/mucinous discharge helps clinicians differentiate between individuals who have very minimal pus from those where more than half of the sinus is occupied by pus or mucin. Scarring is a binary category that ranges from 0 (no scarring) to 1 (scar tissue present). To capture the maximum extension of nasal polyps, we incorporated elements of the NPS proposed by the European Academy of Allergy and Clinical Immunology [6] into our system, making the transition easy for anyone familiar with the latter score (Figure 1). Video 1 demonstrates how to use the SiNES system while performing a standard sinonasal endoscopy.

The SiNES can be quickly obtained while doing a standard nasal endoscopy and is easily recorded using Table 1. However, it can also be recorded using "short notation" to facilitate data capture in the clinic. When using short notation, edema is recorded as a number (ranging from 0 to 4), the discharge domain is written as a letter, and the word "scar" is added in the presence of scar tissue. For example, a sinus with polypoid edema (i.e., 3 in the edema subdomain) with moderate mucin (3 in the discharge subdomain) and scar tissue (1 in the scar subdomain) would be 3M-scar (Video 1).

If an aggregate score is required for research purposes, it can be calculated by adding the mean scores for each category (Table 1). The final aggregate score is kept to one decimal place. Finally, if a particular anatomical site is inaccessible due to scar tissue, normal anatomical barriers, or large polyps, it is given an X and is not computed in the aggregate score.

Population under study for the SiNES validation

We included patients who were diagnosed with CRS with or without nasal polyps according to the EPOS 2020 and ICAR guidelines [15,16]. All patients had a history of at least one endoscopic sinus surgery prior to inclusion. Patients with a history of sinonasal tumors, anterior skull base approaches, or secondary causes of CRS (e.g., cystic fibrosis, granulomatosis with polyangiitis, etc.) were excluded from the study. Patients were recruited from two

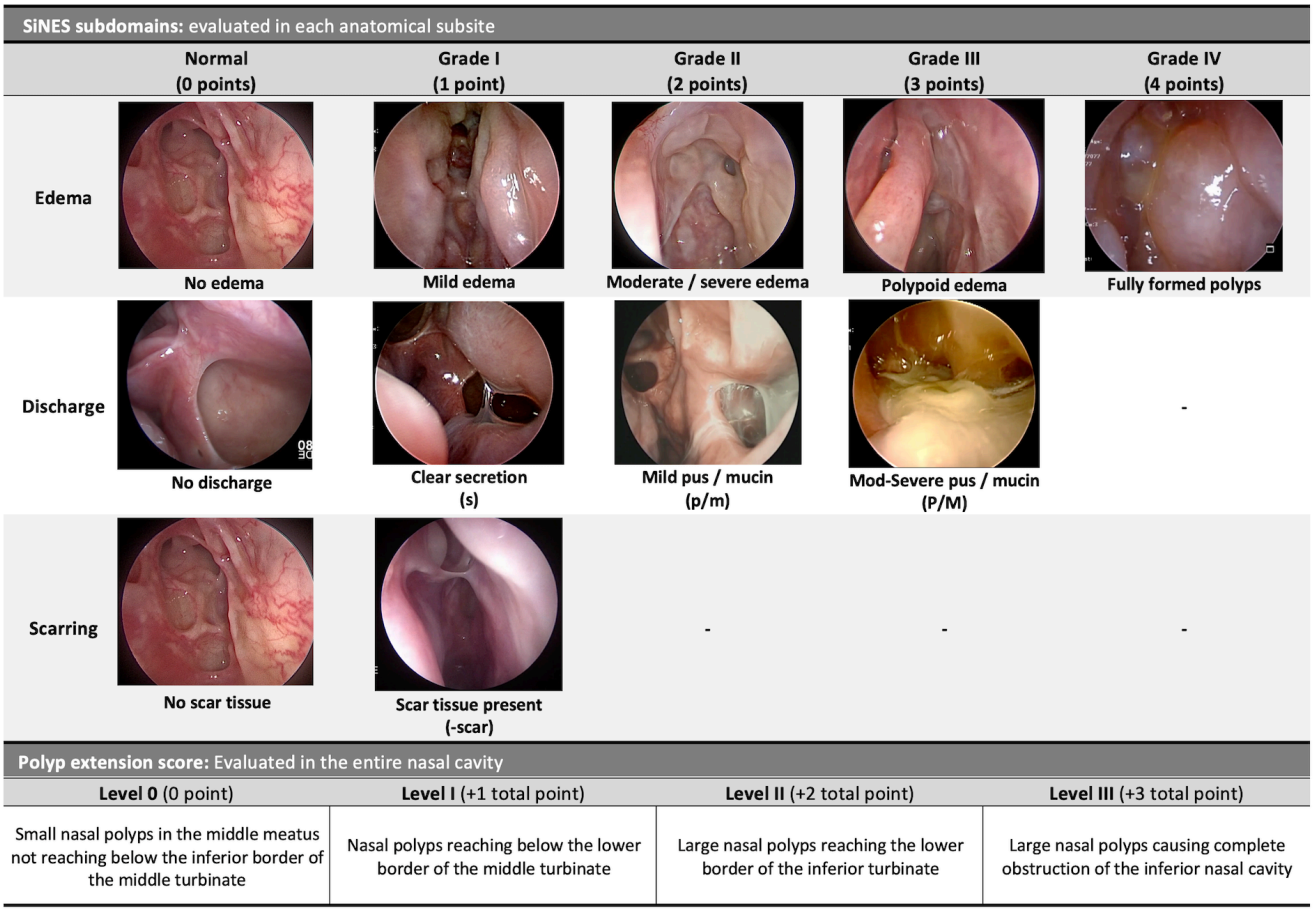

Figure 1. Proposed grading scheme for the SiNES system. Endoscopic pictures for the edema and scaring subdomain correspond to left frontal sinuses. All the pictures for the discharge subdomain correspond to left maxillary sinuses. The proposed short notation for the discharge and scarring subdomains is shown below each category.

separate rhinology clinics, one in Vancouver, Canada and the other in Riyadh, Saudi Arabia.

Patient surveys and endoscopic videos

Participants filled out a SinoNasal Outcomes Test (SNOT-22)[17,18], visual analogue scale (VAS) scores for nasal, allergy, breathing and smell related symptoms, and underwent a systematic sinonasal endoscopy by a trained rhinologist as part of their regular follow-up visits. Questionnaire responses were recorded and stored in an encrypted database until final analysis. Endoscopic videos were anonymized and stored in a cloud drive accessible only to the researchers. No personal identity information was kept in the questionnaire database or endoscopic videos to avoid privacy breaches.

Instrument validation

Face validity subjectively evaluates how much the instrument measures the concept of interest. Similarly, content validity analyzes whether the instrument covers all aspects of the phenomenon in question. Both face and content validity were explored by guided discussions with predefined questions among the four participating rhinologists. The findings from the previous discussions were corroborated by a group of independent rhinologists and general otolaryngologists during a rounding session at the UBC Otolaryngology Department.

Convergent validity measures whether the test in question can achieve a similar response to a different instrument that evaluates the same concept. For this study, we evaluated convergent validity by comparing the MLK and SiNES systems using a Spearman correlation.

Inter-rater reliability was investigated by having three independent rhinologists evaluate the endoscopic videos of patients with various degrees of CRS, including CRSsNP and CRSwNP. The degree of inter-rater reliability was investigated using two different statistical methods, the Intraclass Correlation coefficient (ICC) and the Kendal's Tau.

Test-retest reliability was evaluated by having the three rhinologists grade the same endoscopic videos after two months. Again, the degree of reliability was investigated using both the ICC and Kendal's Tau. ICCs were calculated using random effects

Table 1. SiNonasal Endoscopic Score (SiNES) grading scheme (one table for each side).

	Edema (0-4 pts)	Discharge (0-3 pts)	Scaring (0-1 pts)
Olfactory cleft			
Frontal sinus			
Ethmoid sinus			
Sphenoid sinus			
Maxillary sinus			
Polyp extension score			
Level 0 (+0 total pts)	Level I (+1 total pts)	Level II (+2 total pts)	Level III (+3 total pts)

* Each anatomical space is graded individually for each of the three subdomains. The Polyp extension score is calculated for the entire nasal cavity. Finally, the total SiNES score for that side is calculated by adding the mean value of each SiNES subdomain to the polyp extension score as follows (one per side): TOTAL SiNES = $Edema_{mean}$ + $Discharge_{mean}$ + $Scaring_{mean}$ + Polyp Extension

models in single raters, evaluating consistency and agreement for intra-rater and interrater reliability, respectively. The ICCs were interpreted as follows: Less than 0.5 as poor reliability, 0.5-0.75 as a moderate reliability, 0.76-0.89 as a good reliability, and 0.90 or above as an excellent reliability [19]. We decided on a sample size of 80 individuals since it was the minimum number of patients required to demonstrate an ICC of 0.88 (equal to MLK [1] with a 95% confidence level, 2 repetitions, and no dropouts.

Correlation with patient reported outcome measures (PROMs)
We investigated the association between total and individual SiNES values and PROMs using a Spearman correlation and canonical correlation analysis (CCA) [14]. The latter statistical method maximizes the linear relationship (i.e., canonical correlation) between two sets of variables, each summarized by a canonical function (CF). Specifically, we explored the relationship between the SiNES subdomains (SiNES CF) and the total symptom score, self-reported smell loss, and the four SNOT-22 subdomains (symptoms CF). Furthermore, we explored whether adding weights based on canonical loadings improved the Spearman correlation with symptom scores. MLK values were also correlated with PROMs for benchmark comparisons. We considered correlations as significant if the p-value was < 0.0005 to account for multiple testing (Bonferroni correction). All calculations were done using R version 4.0.3.
The study was approved by the Research and Ethics board from both institutions (approval H21-03695).

Results

We reviewed 122 patients between the two participating centers from September 2021 to February 2022. After careful analysis, 44 individuals were excluded due to poor video quality, missing PROMs, or due to the presence of exclusion criteria, for a final sample size of 79 individuals. The mean (SD) age was 54 (±15) years, and 41 (51%) individuals were female. Twenty-five patients (31%) had allergic fungal rhinosinusitis, 32 (40%) had CRSwNP, and 22 (27%) had CRSsNP. One CRSwNP patient had NSAID exacerbated respiratory disease. The mean (SD) SNOT-22 score was 28 (±22) pts and the mean (SD) VAS for total sinonasal symptoms was 3.5 (±2.4) pts. Postnasal discharge and smell loss had the highest average scores out of all the investigated symptoms (mean [SD] VAS scores of 3.9 [2.8], and 3.4 [3.3] pts for postnasal discharge and smell loss, respectively).
Face and content validity were deemed satisfactory by four of the study authors (JCH, BA, SA, and AJ) and were later found adequate by an independent panel of rhinologists from the University of British Columbia. No items were considered redundant or missing from the final instrument.
The total SiNES and MLK scores were highly correlated (rho 0.95, $p < 0.001$). Inter-rater reliability was deemed excellent for SiNES and good for MLK scores (SINES ICC [95% CI]: 0.91 [0.87 to 0.94] vs MLK ICC [95% CI]: 0.82 [0.73 to 0.88]). The results were consistent using Kendal's Tau (SiNES Tau 0.71 vs MLK tau 0.73; Table 2). Test-retest reliability was excellent for the three reviewers when using the SiNES system and good when using the MLK score (Table 2). The results were consistent using Kendal's Tau.
The edema and polyp subdomains of the MLK scores were moderately correlated with self-reported smell loss (both rho = 0.405, $p < 0.0005$). The SiNES edema subdomain had the highest correlation with smell loss (rho = 0.427, $p < 0.0005$). The total SiNES had a higher correlation with smell loss compared to the total MLK (rho = 0.415, $p < 0.0005$ vs rho = 0.339, $p < 0.0005$). We did not find significant correlations between endoscopic scores and the total or subdomain-specific SNOT-22 score, or other non-rhinologic symptoms (Figure S1).
Figure 2 summarized the CCA output. The SiNES edema subdomain contributed the most to the SiNES CF, followed by the polyp extension score and discharge. Self-reported olfaction had the largest impact on the symptoms CF when compared to other symptoms. Interestingly, the non-rhinologic subdomains

Table 2. Reliability measures for the SiNonasal Endoscopic Score (SiNES) and the Modified Lund-Kennedy (MLK) scores.

Inter-rater reliability score		
	SiNES	MLK
ICC (95% CI)	0.91 (0.87 – 0.94)	0.82 (0.73 – 0.88)
Kendal's tau	0.71	0.73
	SiNES	MLK
Rater 1		
ICC (95% CI)	0.90 (0.84 – 0.94)	0.87 (0.81 – 0.92)
Kendal's tau	0.95	0.92
Rater 2		
ICC (95% CI)	0.91 (0.86 -0.94)	0.83 (0.75 – 0.89)
Kendal's tau	0.96	0.90
Rater 3		
ICC (95% CI)	0.96 (0.93 – 0.98)	0.90 (0.84 – 0.94)
Kendal's tau	0.97	0.94

CI = Confidence interval; ICC = Intraclass correlation coefficient; MLK = Modified Lund-Kennedy; SiNES = SiNonasal Endoscopic Score

of the SNOT-22 were inversely related to rhinologic symptoms and the SiNES CF. Calculating the total SiNES using weighted averages based on the resulting canonical loads did not improve its correlation with self-reported smell loss, TSS or the SNOT-22 in a meaningful way (unweighted SiNES r = 0.415 vs weighted SiNES = 0.428).

Discussion

The SiNES system is an easy-to-use score that can reliably capture the endoscopic appearance of individual sinuses. Content and convergent validity were deemed adequate, while inter rater and test-retest reliability metrics were comparable – if not better – than the MLK score. The system was purposefully designed to facilitate data capture while performing a standard sinonasal endoscopy and can easily be integrated into any EMR system. Finally, we ensured that the SiNES system captured sufficient information to allow for conversion into other endoscopic systems. Consequently, clinicians and researchers can calculate the exact MLK and NPS scores and estimate the DIP score using our grading scheme (Table 3).

Improvements over other endoscopic scores

As noted previously, the existing endoscopic scoring systems give an average assessment of the sinonasal cavity, and lack individual sinus scores [1,12]. The SiNES system overcomes this limitation by evaluating each anatomical space independently. When used in the clinical setting, the SiNES system can help identify problematic sinuses and target treatment. For example, it is common for patients to show minimal to no edema except for the frontal sinus recess. Using the SiNES system, the surgeon can quickly review these scores and adjust their treatment plan accordingly. Similarly, recalcitrant CRS localized to one sinus cavity (e.g., maxillary sinus) can be easily identified and followed using our system. Finally, the SiNES system includes the OC as an individual space. The latter is an important addition to endoscopic grading systems since it allows for improved monitoring of CRS patients with smell loss [20,21]. Moreover, it can help identify patients with isolated central compartment disease from those with more extensive inflammation.

One significant advantage over previous systems is its applicability to any CRS subtype. There is an increasing trend towards CRS endotyping and precision medicine [22–25]. By using the SiNES system, researchers can classify patients according to their endotype (regardless of polyp status) and analyze the results using the same scoring system. The SiNES system allows for a wide range of variation that is not limited by phenotype. Thus, ceiling and floor effects are reduced. For example, mild to moderate edema in CRSwNP – which is an early sign of recurrence – can be accurately detected and graded; something which would not be possible using the NPS alone.

Correlation with PROMs

Our results show that overall edema correlates with self-reported smell loss, regardless of the system used. However, this correlation was maximized by the SiNES edema subdomain. This was achieved by including the presence of polyps into the score and by adding the OC as an anatomical site. Consequently, the spearman correlation improved from a 0.405 (MLK edema and polyp subdomains) to a 0.427 (SiNES edema subdomain). Furthermore, this correlation persists for the total SiNES score (rho = 0.415, p< 0.0005) but not the total MLK (rho = 0.339, p > 0.0005). Thus, the SiNES system improves the correlation with self-reported smell loss.

We did not find significant correlations between endoscopic scores and the SNOT-22. This is not surprising given previous data showing little to no correlation between endoscopic findings and PROMs [26,27]. However, CCA gives some insight into the reasons behind this mismatch. As Figure 2 shows, self-reported smell loss and the nasal subdomain of the SNOT-22 are directly related to the SiNES subdomains, while the non-rhinologic domains are inversely related. In other words, patients with high SNOT-22 scores in non-rhinologic categories tended to have low endoscopic scores. Moreover, the TSS is largely impacted by non-rhinologic symptoms, as shown by the moderate to large correlation between TSS and non-rhinologic subdomains (Figure S1). Thus, we hypothesize that non-rhinologic symptoms are likely affected by other factors like chronicity, environmental exposures, or the patients overall mental health, which are not directly related to endoscopic findings. Additionally, the slow

Table 3. Proposed equivalency table between the SiNES and other endoscopic scoring systems.

SiNES system+	Modified Lund Kennedy	Nasal polyp score	Discharge, inflammation, and polyps/edema scoring system++
Edema subdomain	Edema subdomain	-	Inflammation / edema subdomains*
(0) None	(0) Absent	-	(0) No inflammation / [0] normal mucosa
(1) Mild	(1) Mild	-	(3) Mild inflammation / [3] mild edema
(2) Moderate/Severe	(2) Severe	-	(5) Moderate inflammation / [5] severe edema
(3) Polypoid	(2) Severe	-	(10) Severe inflammation / [6] polypoid edema
(4) Fully formed polyps	(2) Severe	NPS ≥ 1	(10) Severe inflammation / [≥ 7] see below
Discharge subdomain	Discharge subdomain	-	Discharge subdomain
(0) None	0) No discharge	-	(0) Absent discharge
(1) Clear discharge	(1) Clear, thin discharge	-	(5) Thick mucus
(2) Mild pus or mucin	(2) Thick, purulent discharge	-	(10) Purulent discharge
(3) Severe pus or mucin	(2) Thick, purulent discharge	-	(10) Purulent discharge
Scaring subdomain	NA	NA	NA
(0) Absent	-	-	-
(1) Present	-	-	-
Polyp extension score	Polyp subdomain	Total score	Polyp / Edema subdomain
Level 0	(0-1) Absent or within the MM**	Grade 0 or 1 polyps**	(≤6) See above
Level I	(2) Beyond the middle meatus	Grade 2 polyps	(7) Small polyps
Level II	(2) Beyond the middle meatus	Grade 3 polyps	(8) Medium polyps
Level III	(2) Beyond the middle meatus	Grade 4 polyps	(9) Large nasal polyps
			(10) Polyps filling the nasal cavity

+ For each side, the highest score out of the five anatomical sites evaluated in the SiNES system should be used when converting into other systems. ++ The DIP score does not include specific limits in their subdomains, nor does it clearly differentiate between inflammation and edema. Similarly, polyp and edema are combined into a single category. Thus, the corresponding DIP score can be estimated but not converted directly. * To estimate the DIP's Polyp/ edema subdomain, we need to consider the SiNES Edema subdomain and the Polyp extension score. ** If the SiNES edema score is ≤ 3, then the Polyp score is 0 for both the MLK and NPS scores. However, if the SiNES edema score is 4, the MLK and NPS are equal to 1. MLK: Modified Lund Kennedy score; NA: Not applicable; NPS: Nasal Polyp Score; SiNES: SiNonasal Endoscopic Score.

progression of CRS can slowly increase a patient's threshold for pain and discomfort, leading to unusually low symptom and quality of life scores in the presence of severe sinonasal inflammation. These findings highlight the complexity of CRS care and the need for multiple clinical outcome metrics when assessing these patients.

Limitations

Although some aspects of the SiNES score can be used in non-operated patients (e.g., OC edema or the extension subdomain), it was designed for post-surgical surveillance. Thus, it is primarily useful in this patient population. However, we believe this to be a limitation for all endoscopic scoring systems since the mucosa of unopened sinuses cannot be graded. For these cases, tomographic scores are preferred since they give a more accurate picture of disease extension and severity [28,29].

In cases where there is extensive scar tissue or large nasal polyps, scoring individual sinuses might become impossible. In these scenarios, the overall score assumes that the observed and unobserved sinuses are equally diseased. For example, if the sphenoid sinus was not opened during surgery, the overall score would be calculated based on the accessible sinuses and taken as a representative measure of the entire sinonasal space. Similarly, if the maxillary, frontal and sphenoid sinuses cannot be visualized by large ethmoid polyps, the overall score would be the same as if all the sinuses had polyps. Although this is usually the case, there might be scenarios where this assumption does not apply, resulting in measurement error. This limitation is only a concern when using the overall score and does not impair the system's utility in clinical practice. Moreover, it is a limitation present in all endoscopic grading systems and is not unique to our score.

The proposed system – like many others before – assigns a higher weight to the presence of nasal polyps. Nonetheless, it does not imply that patients with CRSwNP will always score higher than those with CRSsNP. For example, someone with small polyps in the ethmoid confined to the middle meatus with no edema in other anatomical sites (i.e., ethmoid edema of 4 with the rest of his sinuses being 0) would score lower than a patient with polypoid edema in every anatomical site (i.e., edema of 3 everywhere); the former would have a mean edema score of 0.8 while the latter would have a mean score of 3. This does not completely avoid discrimination between phenotypes but offers the best alternative when comparing endoscopic severity

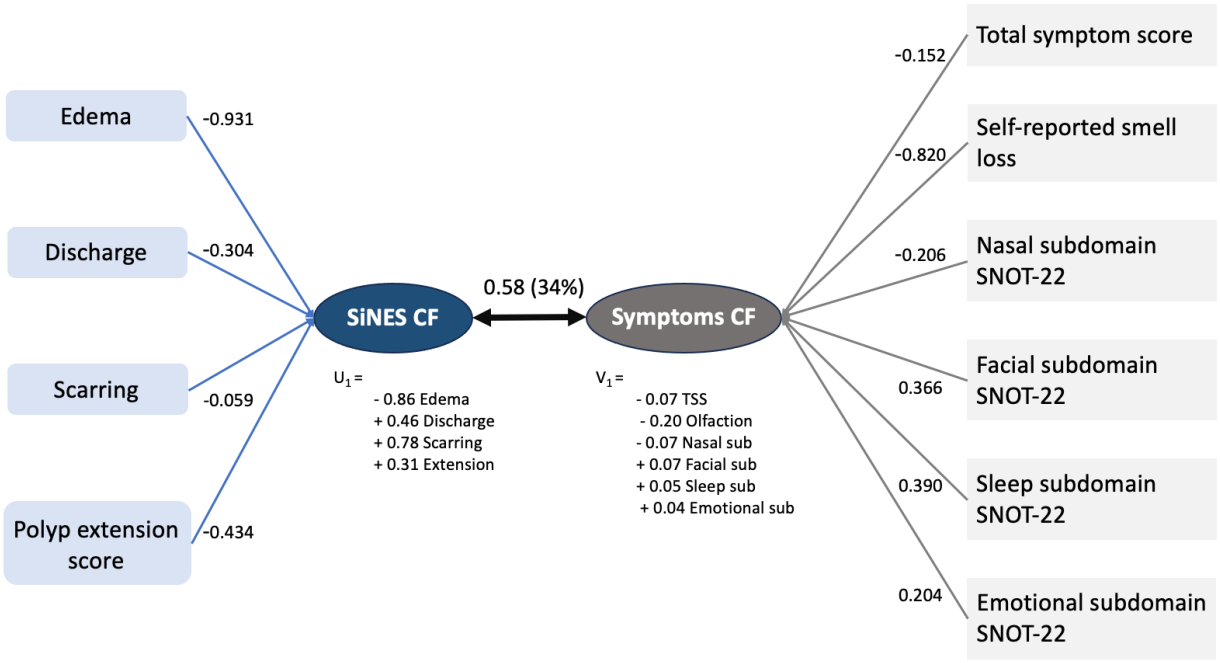

Figure 2. Summary of the CCA. The first CF (U1) includes the SiNES subdomains, while the second CF (V1) includes the TSS, self-reported smell loss, and the SNOT-22 subdomains. CF are shown below their respective names. The correlation between each variable and the corresponding canonical function (i.e., canonical load) is shown besides the variable number. The correlation between both canonical functions (i.e., canonical correlation) is 0.58, which corresponds to 34% of explained variability between both variable groups. The SiNES subdomains are directly related to self-reported smell loss and the nasal subdomain of the SNOT-22 and inversely related to the TSS and non-rhinologic SNOT-22 subdomains. CCA: canonical correlation analysis; CF: canonical function; SNOT-22: Sinonasal outcomes test; TSS: total symptom score.

between patients with and without nasal polyps.

The SiNES system appears complex at first, which might deter some clinicians from using it. However, we believe most readers will find it simple and easy-to-use score upon further inspection. We decided to include a video containing a couple of examples that might further facilitate its understanding and advantages. Finally, we did not report a minimal clinically important difference (MCID) for the SiNES score. It is important to note that none of the current scoring systems have an MCID attached to them. However, we are currently working on a separate study that will try to answer this specific question.

Conclusion

The SiNES system is a reliable endoscopic scoring system that can be applicable to any subtype of CRS. It constructively builds upon previous scoring systems, incorporating some of their strengths, while directly addressing their limitations. It can be easily applied in clinical and research settings, allowing for accurate patient follow-up and detection of subtle but important changes.

Authorship contribution

JCH, BA, AP, SA, and AJ contributed to conception and design: acquisition of data and images; analysis and interpretation of literature; drafting of the manuscript; critical revision of the manuscript; and final approval. JF, KA contributed to the acquisition of data and images; drafting of the manuscript; critical revision of the manuscript; and final approval. SA and AJ share senior co-authorship in this manuscript.

Conflict of interest

The authors of this paper do not have any relevant conflicts of interest to disclose.

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SUPPLEMENTARY MATERIAL

Figure S1. Correlation matrix between endoscopic and clinical variables. The lower left segment of the figure shows a scatter plot for each corresponding variable pair. The upper right segment of the figure shows the Spearman correlation coefficient for each variable pair. Significant correlations are highlighted with a red square ($p < 0.0005$). Corr: Spearman´s Rho; MLK: Modified Lund Kennedy score; OC: Olfactory cleft, sd: subdomain; SiNES: SiNonasal Endoscopic Score; SNOT-22: SiNonasal Outcomes Test; TSS: Total symptom score.