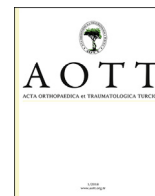


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Analysis of factors affecting baseline SF-36 Mental Component Summary in Adult Spinal Deformity and its impact on surgical outcomes

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ABSTRACT

Objectives: To identify the factors that affect SF-36 mental component summary (MCS) in patients with adult spinal deformity (ASD) at the time of presentation, and to analyse the effect of SF-36 MCS on clinical outcomes in surgically treated patients.

Methods: Prospectively collected data from a multicentric ASD database was analysed for baseline parameters. Then, the same database for surgically treated patients with a minimum of 1-year follow-up was analysed to see the effect of baseline SF-36 MCS on treatment results. A clinically useful SF-36 MCS was determined by ROC Curve analysis.

Results: A total of 229 patients with the baseline parameters were analysed. A strong correlation between SF-36 MCS and SRS-22, ODI, gender, and diagnosis were found ($p < 0.05$). For the second part of the study, a total of 186 surgically treated patients were analysed. Only for SF-36 PCS, the un-improved cohort based on minimum clinically important differences had significantly lower mean baseline SF-36 MCS ($p < 0.001$). SF-36 MCS was found to have an odds ratio of 0.914 in improving SF-36 PCS score (unit by unit) ($p < 0.001$). A cut-off point of 43.97 for SF-36 MCS was found to be predictive of SF-36 PCS (AUC = 0.631; $p < 0.001$).

Conclusions: The factors effective on the baseline SF-36 MCS in an ASD population are other HRQOL parameters such as SRS-22 and ODI as well as the baseline thoracic kyphosis and gender. This study has also demonstrated that baseline SF-36 MCS does not necessarily have any effect on the treatment results by surgery as assessed by SRS-22 or ODI.

Level of evidence: Level III, prognostic study.

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Introduction

The prevalence of Adult Spinal Deformity (ASD) is high worldwide, and the need for surgical deformity correction and relief of symptoms has subsequently increased. Previous research indicates

that in younger subgroup of patients with spine deformity, treatment is directed mainly by the severity of the deformity,¹ however in the elderly, the main decisive factors for treatment are pain, poor function and disability^{2–5} factors that had been demonstrated to be strongly associated with several radiological parameters.⁶ ASD surgery has been shown to yield better results compared to conservative treatment in the overall population of patients in terms of Health Related Quality Of Life (HRQOL) outcomes.^{7,8} However, still a significant proportion of operated patients do not improve following surgery regardless of the apparent technical success or failure of the operations.^{5,9} What is not yet understood is how various clinical parameters of ASD affect the mental well being of patients before treatment and the potential snowball effect of the impact of baseline mental status of a patient on treatment outcomes after surgery. A recent study suggests that ASD may affect the mental and psychological functioning of patients.¹⁰ It is well accepted in others areas of spine that pre-operative psychosocial factors are predictive of outcome and correlates with improvement in QOL after spine surgery.^{11–15} Several studies also suggest that psychosocial questionnaires may serve as standardized tools for identifying patients who are more likely to have positive post-operative outcomes and those who are unlikely to derive the expected benefit from surgery.^{16,17}

SF-36 is a widely used HRQOL tool in spine surgery, commonly broken into two main domains of the Physical Component Summary (PCS) and the Mental Component Summary (MCS). Several publications have demonstrated that SF-36 MCS highly correlates with standard tools used to screen for depressive symptoms.^{18,19} Other studies have shown that SF-36 MCS is an effective screening tool for depression^{20,21} and that; SF-36 MCS cut-off point of 35 is clinically relevant for identifying depressive symptoms in patients with spine pathology.²² This cut-off point has been found to have a sensitivity of 80% and specificity of 90% for patients with back pain.²²

The open questions in regard to the role of the SF-36 MCS in ASD are whether it is strongly affected by other factors (age, other demographic factors, disability) and to what extent it affects the outcome of patients undergoing surgery for ASD. Hence, the specific aims of this study were:

1. To identify the factors that affect SF-36MCS in patients with ASD at the time of presentation, regardless of the severity of deformity, disability and the final treatment decision, and,
2. To analyse, in turn, the effect of SF-36MCS on clinical outcomes in patients treated surgically.

As far as we know this is one of the first report in the literature to directly examine the impact of various HRQOL clinical parameters, on the psychological well being of ASD patients before commencing treatment and the subsequent effect of this, on outcomes after surgery.

Material and methods

Factors affecting SF-36 MCS at baseline

Two hundred and twenty nine patients who had been entered in an ASD database on adult spine deformity and had completed SF-36MCS were analysed. The inclusion criteria into the database and hence for this study was as following; age >18 years and scoliosis >20°, or sagittal vertical axis (SVA) >5 cm, or pelvic tilt >25°, or thoracic kyphosis >60°. All patients were enrolled into an institutional review board approved protocol by the respective sites. All patients with baseline parameters were included (before treatment). Baseline demographic data [age, gender, co-morbidities and body mass index (BMI)], HRQOL parameters [The Core

Outcome Measures Index (COMI), The Oswestry Disability Index (ODI), Short-Form (SF)-36 Mental Component Summary (MCS), SF-36 Physical Component Summary (PCS) and Scoliosis Research Society-22 questionnaire (SRS-22)], the following radiological features were included in the analysis; Sagittal Vertical Axis (SVA), T2-T12 kyphosis, Coronal balance, Major curve Cobb angle, Lordosis Gap (L Gap),⁶ Global Tilt (GT)²³ and T1 sagittal tilt. Patients were also stratified according to the aetiology of their deformity; idiopathic scoliosis, degenerative scoliosis and others.

Statistical analysis

A multivariate linear regression analysis model was built with SF-36MCS as the dependent variable. Demographic, radiological and HRQOL parameters were independent variables for this model. As a first step, a correlation analysis between the SF-36 MCS and all the independent variables was performed using Pearson's correlation coefficient, point bi-serial correlation and Eta coefficient. The purpose of this step was to define and select the candidate independent variables for multivariate linear regression. Sequential multiple linear regressions were used to explain the variation of SF-36 MCS scores. Each independent variable was regressed by sequentially adding the variables to the model starting first with the variable showing the highest correlation with SF-36 MCS. Decision to remove a variable from the model was based on the direction and magnitude of change in the estimate of the parameter with highest correlation as well as of the resulting adjusted-R² values (p-value <0.05). Using a stepwise automatic selection technique, a verification of this model was done. All statistical analysis was performed using the SPSS Statistics 21.0 software (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp).

Impact of SF-36MCS on surgical results

From the same database, one hundred and eighty-six patients (157 women and 29 men) with ASD surgically treated, and with a minimum of one-year follow-up and full documentation were analysed. For this part of the study, the following data was extracted; baseline SF-36 MCS, demographics and HRQOL data (ODI, COMI, SRS-22 and SF-36 PCS) at one-year post surgery. Using the distribution based Minimally Clinically Important Difference (MCID) for each HRQOL parameter calculated from the aforementioned database; patients were dichotomized into two groups of, "un-improved" and "improved" cohorts.²⁴ That is, a patient who had deteriorated in terms of HRQOL or had not reached the MCID for that HRQOL parameter at the 1st year follow-up was categorized as un-improved.

Statistical analysis

The mean values (and SD) of baseline SF-36MCS for each parameter in the "improved" and "un-improved" categories were calculated. Student's t-test was used to compare pre-operative SF-36MCS between improved and un-improved cohorts for each HRQOL outcome measure (p < 0.05).

A univariate binary logistic regression method was then used to analyse the size effect of pre-operative SF-36 MCS on any HRQOL parameter that was statistically significant on Student's t-test. For this model, the pre-operative SF-36 MCS was the independent variable while HRQOL outcome measures were dependent variables (p < 0.05). For the scale (HRQOL) that statistically significant results were obtained, a clinically useful pre-operative SF-36 MCS cut-off point that could predict the likelihood of a patient attaining MCID post surgery was determined by Receiver Operating Characteristic Curve (ROC) analysis (p < 0.05). Statistical analysis was performed using the same the SPSS Statistics 21.0 software (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp).

Results

Factors affecting SF-36 MCS before treatment

Of the two hundred twenty nine (n = 229) patients analysed in this part of the study, one hundred and eighty one (79.4%) were females and forty-seven (20.6%) were males. Mean age was 49.4 years with a range of 18–85 years. Eighty one (n = 81) patients had co-morbidities, one hundred and forty-eight (n = 148) did not. Ninety-nine patients (43.4%) had idiopathic scoliosis, eighty five (28.5%) had degenerative scoliosis and eighteen patients (7.9%) had other causes of deformity. All patients had complete SF-36 MCS tool, whereas two hundred and five had complete (n = 205) SRS-22, one hundred and ninety eight (n = 198) had complete ODI and two hundred and twenty nine (n = 229) had complete SF-36 PCS (Table 1).

Correlation of baseline SF-36MCS with demographic parameters and HRQOL

There was a strong correlation between baseline SF-36 MCS and baseline SRS-22 and ODI scores with Pearson's correlation coefficients of 0.462, 0.392 respectively, and p value < 0.001 for both. Further, gender (point bi-serial correlation coefficient of 0.150, p value = 0.02) and diagnosis before treatment (Eta coefficient 0.242, p value = 0.010) were found to have significant correlations with baseline SF-36 MCS (Table 2). To evaluate the multi-co linearity between predictor variables for multiple linear regression, correlations between candidate variables were dealt with (Table 3). No multi-co linearity was found amongst independent variables and no variable dimension had more than one variance proportion greater than 0.50.

Regression analysis

Our regression model supported that results were normally distributed and this model met all assumptions as shown in (Fig. 1). R² is statistically significant F (3,139) = 15.816; (p < 0.001) but only for 0.254 of the study sample. Regression analysis shows that for one unit increase in pre-operative SRS-22, a corresponding increase in the SF-36MCS score by a factor of 0.403 (p < 0.001) is to be expected (ODI was omitted from this analysis because of a strong correlation with it and the SRS-22, a similar trend should apply to the ODI as well). Likewise, one unit (degree) increase in T2-T12 kyphosis decreases SF-36 MCS score by a factor of 0.194 (p = 0.012). Male gender has increased baseline SF-36 MCS by a factor of 0.197 (p = 0.013) compared to females (Table 4).

Impact of SF-36MCS on surgical results

A total of one hundred and eighty-six (n = 186) patients who had complete SF-36MCS data and one-year follow-up were analysed in this part of the study. One hundred and fifty seven patients were females (n = 157) and twenty-nine were males (n = 29). There was no statistically significant difference in mean pre-operative SF-36MCS between the surgically “improved” and “un-improved” patients for ODI (p = 0.487). Similarly, there was no statistically significant difference in mean pre-operative SF-36MCS between

Table 1
Number of patients completed the HRQOL questionnaires before treatment and their means.

	SF-36 MCS	SRS-22	ODI	SF-36 PCS
n	229	205	198	229
Mean ± Std. Dev.	41.4 ± 11.8	2.9 ± 0.7	41.3 ± 22.1	36.5 ± 9.1

Table 2
Correlations between SF-36 MCS and clinical variables.

Variables	Pearson correlation coefficient	p value
SRS-22	0.462	<0.001
ODI	-0.391	<0.001
SF-36 PCS	-0.037	0.578
Age	-0.111	0.092
BMI	-0.125	0.067
Sagittal balance parameters	-0.135	0.051
Coronal balance	0.039	0.567
T2-T12	-0.091	0.189
Coronal maximum Cob angle	0.115	0.103
Lgap	0.033	0.636
Global tilt	-0.126	0.068
T1 sagittal tilt	-0.032	0.654
Major Curve Cobb Angle	0.115	0.103
Point biserial correlation		P value
Gender	0.150	0.02
Comorbidities	0.060	0.39
Eta coefficient		P value
Diagnosis	0.242	0.010
SRS-Schwab Coronal	0.172	0.025
SRS-Schwab Sagittal PI-LL	0.118	0.360
SRS-Schwab Sagittal PT	0.093	0.630
SRS-Schwab Sagittal SVA	0.106	0.420

surgically “improved” and “un-improved” patients for COMI and SRS-22 (p values = 0.881 and 0.415, respectively). On the other hand for SF-36 PCS, this difference was found to be significant; the “un-improved” cohort has a significantly lower mean pre-operative SF-36MCS compared to the “improved” cohort (p = 0.025) (Table 5).

Univariate binary regression analysis

Since SF-36 PCS was the only HRQOL parameter significant on the t-test, it was the only one included in regression analysis. It was hence found that one unit increase of baseline SF-36 MCS increases the probability of improvement by SF-36 PCS by a factor of 0.914 (p < 0.001). The optimum cut-off for pre-operative SF-36 MCS that provides distinct differentiation between the un-improved and improved by SF-36 PCS was found to be 43.97 (AUC = 0.604; p = 0.020), i.e., those patients with SF-36MCS values lower than 43.97 have a significantly lower chance of improvement in SF-36 PCS by surgery.

Discussion

This study aimed to analyse the factors affecting the baseline SF-36 MCS values of patients with adult spinal deformity and whether SF-36 MCS in turn affects the clinical outcomes (in terms of HRQOL parameters) following surgery. Our results suggest that factors highly correlating with baseline SF-36 MCS are baseline SRS-22 and ODI, the magnitude of thoracic kyphosis and gender. In addition this study further demonstrated that the common intuitive belief that those patients with lower MCS scores might not do as well as their counterparts with higher holds only for SF-36 PCS, with a cut-off value for MCS of 43.97.

Some of these findings are somewhat predictable whereas some are particularly interesting in several ways. Firstly, knowing that most HRQOL parameters correlate with each other, it may not be surprising to see that the baseline SF-36 MCS has a very strong correlation with both these tests. As our disability and/or dissatisfaction due to ASD increases, we are expected to acquire a lower mental status. The interesting point here though might have been the distinction between the SRS-22 and ODI that has been shown to

Table 3
Correlations between candidate clinical variables with statistical significance $p < 0.25$.

Variables		SRS22	ODI	Age	BMI	SVA	T2 T12	Coronal Maximum Cobb	Global tilt	Major Curve Cobb	Gender	Diagnosis	SRS-Schwab Coronal type
SRS22	rho		-0.705	-0.362	-0.284	-0.321	-0.001	0.177	-0.426	0.177	0.179	0.118	-0.194
	p		<0.001	<0.001	<0.001	<0.001	0.984	0.016	<0.001	0.016	0.010	0.091	0.006
ODI	rho			0.523	0.424	0.296	-0.175	-0.297	0.384	-0.297	-0.251	-0.328	0.199
	p			<0.001	<0.001	<0.001	0.017	<0.001	<0.001	<0.001	<0.001	<0.001	0.005
Age	rho				0.423	0.385	-0.077	-0.290	0.592	-0.290	-0.121	-0.394	0.145
	p				<0.001	<0.001	0.263	<0.001	<0.001	<0.001	0.068	<0.001	0.030
BMI	rho					0.167	0.008	-0.228	0.213	-0.228	0.011	-0.174	0.206
	p					0.018	0.912	0.001	0.003	0.001	0.877	0.010	0.003
SVA	rho						-0.180	-0.173	0.679	-0.173	0.089	-0.291	0.146
	p						0.011	0.016	<0.001	0.016	0.199	<0.001	0.034
T2-T12	rho							-0.021	-0.165	-0.021	0.234	0.247	0.152
	p							0.775	0.020	0.775	0.001	<0.001	0.027
Coronal maximum Cobb	rho								-0.240	1.000	0.023	-0.014	-0.616
	p								0.001	<0.001	0.742	0.847	<0.001
Global tilt	rho									-0.240	-0.105	-0.318	0.141
	p									0.001	0.132	<0.001	0.042
Major Curve Cobb	rho										0.023	-0.014	-0.616
	p										0.742	0.847	<0.001
Gender	rho											0.215	0.031
	p											0.001	0.648
Diagnosis	rho												0.011
	p												0.873

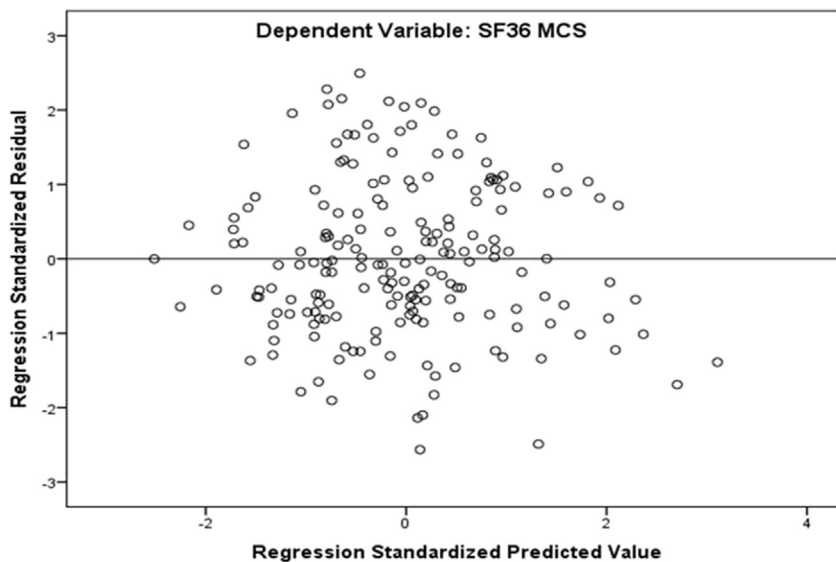


Fig. 1. Distribution plot demonstrating all assumptions are met for this regression analysis model.

Table 4
Multiple linear regression analysis measuring influence of clinical parameters on pre-operative SF-36 MCS.

Model	Standardized coefficients	t	p
Constant		4.518	<0.001
SRS-22	0.403	5.344	<0.001
T2-T12	-0.194	-2.557	0.012
Gender	0.197	2.522	0.013

exist in previous studies,⁸ but had not appeared in this study. This may be explained by the heterogeneity of the patient group that had been analysed in this study; those younger patients predominantly affected by their appearances (better reflected by SRS-22), are balanced by the older ones who are not necessarily disturbed by their appearances but rather the disability caused by their

deformities (better reflected by ODI). Hence, a breakdown of the patient population in a larger study in the future may identify the specific effects of these two different HRQOL parameters on SF-36 MCS separately.

The authors of this study tended to interpret the effect of thoracic kyphosis angle on SF-36 MCS potentially as one related to appearance. It is particularly interesting that kyphosis and kyphosis only, appears to be important rather than the magnitude of the major coronal curve and/or coronal or sagittal balance parameters that may also affect not only appearance but disability as well. In this respect, SF-36 MCS appears to be significantly different from other HRQOL parameters for which the most important governing factor had been shown to be sagittal balance and the aetiology of the deformity.²⁵ This being said, we may also consider that extreme cases of thoracic kyphosis may also be associated with a higher degree of pain and/or respiratory problems, both of which being

Table 5

Pre-operative SF-36 MCS of improved group and un-improved group of patients as determined by MCID for ODI, COMI, SF-36 PCS and SRS-22 by t-test.

		Baseline SF36MCS	p
		Mean (std.dev.)	
ODI	Un-improved	38.89 (8.25)	0.487
	Improved	41.45 (11.95)	
COMI	Un-improved	42.09 (8.34)	0.881
	Improved	41.22 (11.46)	
SF-36 PCS	Un-improved	39.35 (11.14)	0.025
	Improved	43.44 (12.07)	
SRS-22	Un-improved	42.17 (11.12)	0.415
	Improved	40.65 (12.13)	

factors increasing disability. Hence, the importance of thoracic kyphosis in determining the baseline SF-36 MCS may be multifactorial, affected by appearance as well as disability of patients.

The effect of gender on the other hand is one that has been shown by other studies as well.^{25–28} This is probably due to the different coping mechanisms of genders with the problems associated with ASD, be it appearance or pain and disability or both. Research consistently demonstrates that men and women differ in their responses to pain and there are multiple psychosocial processes that contribute to this difference.²⁹ While men tend to use more behavioural distraction and problem-focused strategies to cope with pain, women are more likely to cope with emotion-oriented behaviours and to seek social support.^{28,30} There is also an association between gender and quality of life. Research shows that females have poorer quality of life than males.³¹ It is possible to explain this by various mediators such as differences in perceived social support,³² catastrophizing³³ and self-efficacy.³⁴ Perceived social support is somehow measured by the MCS and as stated before it is a crucial coping mechanism for women. Therefore it is not surprising to see that females reported less emotional well-being (lower MCS scores) than men in this study. Similarly, catastrophizing seems to be mediating gender differences in pain experience and hence self-reported quality of life. Research has shown that women engage in catastrophic thinking more than men, especially in terms of rumination and helplessness.³⁵ Therefore, it is possible that women focus more on their deformity/pain and exaggerate it more than men. And finally, self-efficacy, one's belief that one can successfully perform a behaviour to achieve a goal, could explain the lower emotional QOL in women. Evidence has indicated that women generally demonstrate lower self-efficacy than men, and a lower degree of self-efficacy is associated with higher levels of pain. So, in the present study it is possible that various psychosocial mechanisms have contributed to the lower emotional QOL scores observed in women.

The importance of this finding therefore does not necessarily lie in the fact that it has been found significant, but rather in its potential effect on treatment decisions in patients with ASD. It may be important for the surgeons and/or other decision makers to understand that although females appear more prone to be affected by ASD mentally, this does not necessarily mean that surgery (or any other treatment modality) will be less effective in improving their HRQOL, as has been shown by other studies.⁸ This finding therefore is the materialisation of a natural phenomenon in this specific subject and not necessarily anything else.

As has been summarized above, the potential effects of the mental status of patients have been scrutinised for many pain and disability related spinal conditions.^{11–17} Based on this background, the finding that baseline SF-36 MCS does not necessarily affect the outcome at the first year after surgery for both SRS-22 and ODI appears surprising. The only significantly affected factor was found to be the SF-36 PCS, for which a SF-36 MCS cut-off point of 43.97

could be identified. These findings may be explained in several ways. One would be the face value explanation, as indirectly discussed on the matter of gender above, the fact that a patient with ASD should not necessarily mean that the surgical (treatment) outcomes in this patient would be less satisfactory. This line of thought follows the argument that ASD is a very complex blend of several problems (deformity itself, pain, spinal stenosis, disability) that may individually be affected by the baseline mental status of those involved in terms of treatment outcomes but not so when they blend with each other. The relative insensitivity of the disease specific HRQOL measures (SRS-22 specific for deformity and ODI and COMI specific for back related disability) compared to the relative sensitivity of a generic HRQOL measure (SF-36PCS) may support this explanation. Another (fairly obvious) explanation of the relative sensitivity of the treatment outcomes by SF-36 PCS may be that this measure and SF-36 MCS originate and are calculated from the same set of questions and are therefore expected to be very highly correlated and/or affected by each other in any case. What might have been interesting to analyse would be to perform a similar study on patients who had not been treated surgically (or, not at all) to see whether the outcomes by SF-36 PCS would be affected by the SF-36 MCS. This may be elaborated by future studies.

This study has several minor shortcomings. One is our inability to include a large number of patients from the database due to the incompleteness of their SF-36MCS data. The present patient number allows for a fairly high statistical power but apparently, inclusion of a larger number of patients would have made this study even stronger. Secondly, one year followed up had been chosen arbitrarily as it has been thought that one year may be the time that the treatment effects (on baseline parameters) may be at their peak, but it may not be so and the effects of baseline HRQOL parameters may still ensue at longer follow-up periods. Thus future work should also include similar analyses at longer follow-up points. And thirdly, as discussed above, the lack of a control group (of another type of treatment and/or no treatment) needs to be considered as a shortcoming as well. This study has provided information on the effect of SF-36 MCS on treatment results for surgical ASD patients but we still do not have this particular information for non-surgical patients.

Conclusion

This study has demonstrated that the factors effective on the baseline SF-36 MCS in an ASD population are other HRQOL parameters such as SRS-22 and ODI as well as the baseline thoracic kyphosis and gender. There is parallelism between the HRQOL parameters whereas those patients with higher thoracic kyphosis and females have lower SF-36 MCS values. On the other hand, this study has also demonstrated that baseline SF-36 MCS does not necessarily have any effect on the treatment results by surgery as

assessed by SRS-22 or ODI. Only outcomes by a non disease specific test, the SF-36 PCS at the first year was found to be significantly affected by baseline SF-36 MCS, a finding that may be explained by the complexity of ASD as a medical problem.

Conflicts of interest

The authors of this manuscript declare the conflicts of interests disclosed below, which are not directly or indirectly related to the results and discussions provided in this manuscript.

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