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## Baseline Frailty Status Influences Recovery Patterns and Outcomes Following Alignment Correction of Cervical Deformity

**BACKGROUND:** Frailty severity may be an important determinant for impaired recovery after cervical spine deformity (CD) corrective surgery.

**OBJECTIVE:** To evaluate postop clinical recovery among CD patients between frailty states undergoing primary procedures.

**METHODS:** Patients >18 yr old undergoing surgery for CD with health-related quality of life (HRQL) data at baseline, 3-mo, and 1-yr postoperative were identified. Patients were stratified by the modified CD frailty index scale from 0 to 1 (no frailty [NF] <0.3, mild/severe frailty [F] >0.3). Patients in NF and F groups were propensity score matched for TS-CL (T1 slope [TS] minus angle between the C2 inferior end plate and the C7 inferior end plate [CL]) to control for baseline deformity. Area under the curve was calculated for follow-up time intervals determining overall normalized, time-adjusted HRQL outcomes; Integrated Health State (IHS) was compared between NF and F groups.

**RESULTS:** A total of 106 CD patients were included (61.7 yr, 66% F, 27.7 kg/m<sup>2</sup>)—by frailty group: 52.8% NF, 47.2% F. After propensity score matching for TS-CL (mean: 38.1°), 38 patients remained in each of the NF and F groups. IHS-adjusted HRQL outcomes from baseline to 1 yr showed a significant difference in Euro-Qol 5 Dimension scores (NF: 1.02, F: 1.07,  $P = .016$ ). No significant differences were found in the IHS Neck Disability Index (NDI) and modified Japanese Orthopedic Association between frailty groups ( $P > .05$ ). F patients had more postop major complications (31.3%) compared to the NF (8.9%),  $P = .004$ , though DJK occurrence and reoperation between the groups was not significant.

**CONCLUSION:** While all groups exhibited improved postop disability and pain scores, frail patients experienced greater amount of improvement in overall health state compared to baseline disability. This signifies that with frailty severity, patients have more room for improvement postop compared to baseline quality of life.

**KEY WORDS:** Cervical deformity, CD, Recovery kinetics, Frailty

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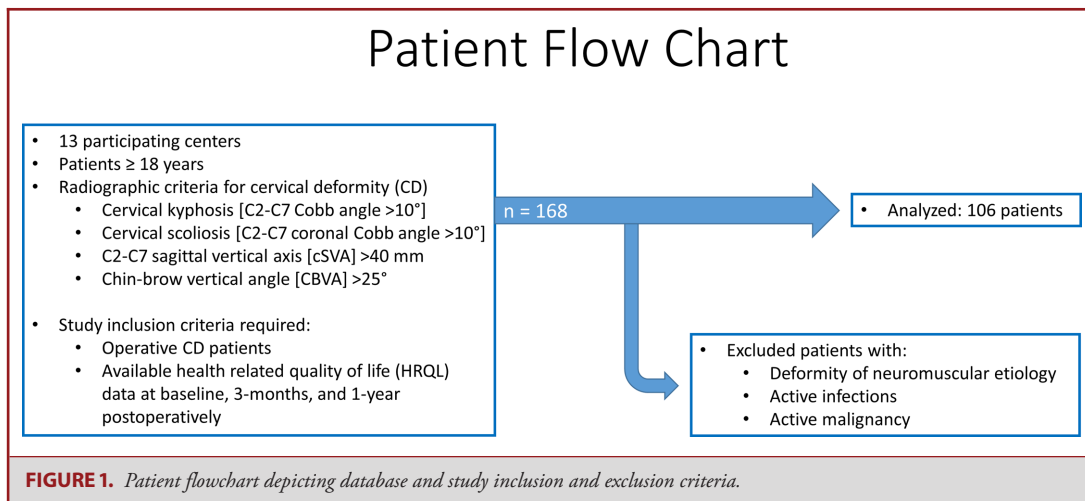
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**F**railty status of a patient is a measure that incorporates comorbidity status and functionality. This physiological measure surpasses the traditional chronological age in terms of preoperative health assessment. Several studies have noted that risk of poor postoperative outcomes increases with increasing

frailty.<sup>1</sup> Recently, a frailty index has been developed in a cervical deformity population (Miller et al) and modified in 2019 study by Passias et al, which is correlated with mortality and postoperative complications, and may serve as accurate and useful risk stratification metric.<sup>2,3</sup>

**ABBREVIATIONS:** CBVA, chin to brow vertical angle; CD, cervical spine deformity; EQ5D, Euro-Qol 5 Dimension; HRQL, health-related quality of life; IHS, Integrated Health State; mCD-FI, modified cervical deformity frailty index; MCID, minimally clinically important difference; mJOA, modified Japanese Orthopedic Association; NDI, Neck Disability Index; NF, no frailty; NRS-Neck, numeric rating scale neck; PSM, propensity score matched; SVA, sagittal vertical axis

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Cervical spine deformity (CD) surgery has often been associated with a high rate of complications and given the number of frail adult patients undergoing elective correction, accurate assessment of baseline frailty status is increasingly important to understand the recovery trajectory of each individual patient.<sup>4</sup> Prior studies of CD populations and frailty indices have assessed patient physical recovery, noting that with increase in frailty severity, perioperative outcomes deteriorate.<sup>5,6</sup> Few studies exist to compare clinical patient-reported outcomes, rather than just physical recovery, among frailty statuses across follow-up time points.

A methodology involving use of the area under the curve (AUC) accounts for recovery patterns across patients categorized into different groups and was utilized in the present study for frailty status.<sup>7</sup> By normalizing follow-up data on patient-reported outcomes relative to the preoperative score, frailty status impact on recovery may be accurately assessed by accounting for floor and ceiling effects of baseline health-related quality of life (HRQL) scores. By plotting the normalized scores against follow-up time points upon a graph, the AUC is generated which quantifies a patient's recovery trajectory across a given timespan.<sup>8</sup> The objective of this study was to discover recovery patterns of cervical deformity patients in differing frailty groups for various HRQL metrics.

## METHODS

### Data Source

Developed by the International Spine Study Group (ISSG), we retrospectively analyzed a prospectively collected database enrolled at 13 participating centers from 2013 to 2018. Through Institutional Review Board approval and informed patient consent, the database was created including patients greater than 18 yr of age meeting radiographic criteria of cervical deformity (cervical kyphosis [C2-C7 Cobb angle  $>10^\circ$ ], cervical scoliosis [C2-C7 coronal Cobb angle  $>10^\circ$ ],

C2-C7 sagittal vertical axis [cSVA]  $>40$  mm or chin to brow vertical angle [CBVA]  $>25^\circ$ ) with plans to undergo surgical intervention. Patients with deformity of neuromuscular etiology or those with active infections or malignancy were excluded from the database. The study inclusion criteria required CD patients with available HRQL data at baseline, 3-mo, and 1-yr, postoperatively (Figure 1).

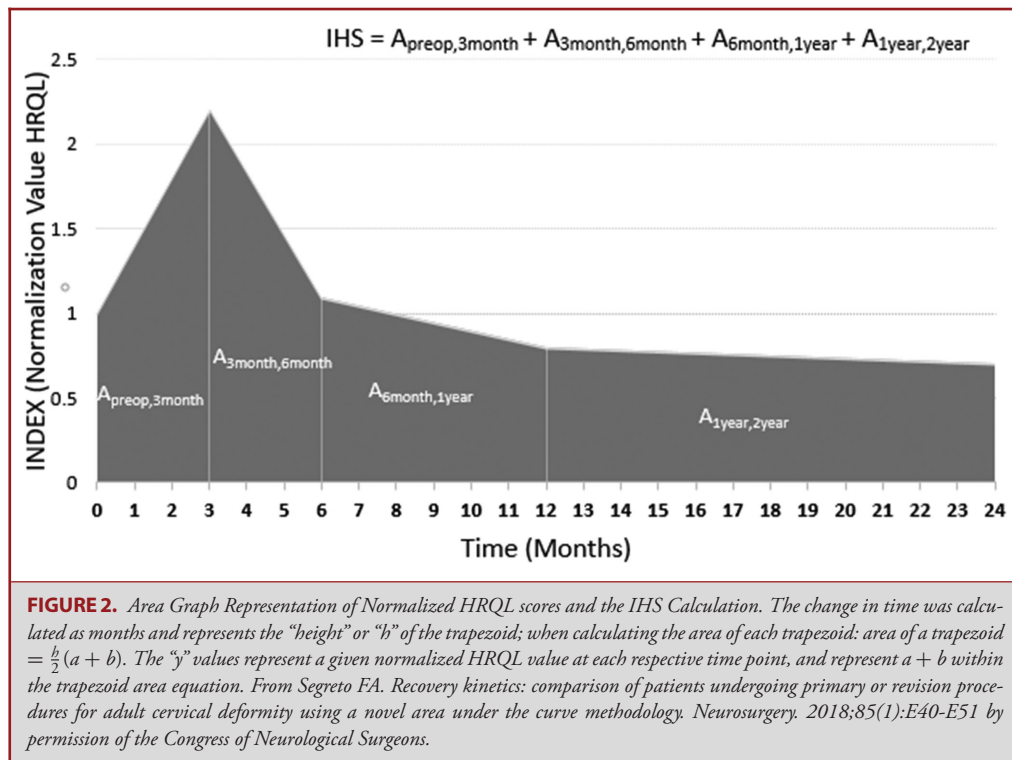
### Data Collection and Radiographic Assessment

To assess frailty status, the modified cervical deformity frailty index (mCD-FI) was utilized.<sup>2</sup> HRQL questionnaires were collected preoperatively and at 3-mo and 1-yr follow-up time points. Those included the Neck Disability Index (NDI), numeric rating scale neck (NRS-Neck), Euro-Qol 5 Dimension (EQ5D), and the modified Japanese Orthopedic Association (mJOA) metrics.

Full-length free-standing lateral spine radiographs were used to assess CD patients at baseline and follow-up intervals, and analyzed with SpineView<sup>®</sup> (ENSAM, Laboratory of Biomechanics, Paris, France).<sup>9-11</sup> Spinopelvic parameters analyzed included pelvic tilt (PT: the angle found from the vertical line and the line through the sacral midpoint to the center of both femoral heads), the mismatch between pelvic incidence and lumbar lordosis (PI-LL), and the SVA (C7 plumb line in reference to the posterosuperior corner of S1).<sup>12</sup> Cervical parameters assessed included cervical kyphosis, cervical scoliosis (CL: angle between the C2 inferior end plate and the C7 inferior end plate), C2-C7 SVA (cSVA: C2 plumbline offset from the posterosuperior corner of C7), chin brow vertical angle (CBVA), and T1 slope minus CL (TS-CL: mismatch between T1 slope and cervical curvature).

### Statistical Analysis

Statistical analysis was performed using SPSS software (version 21.0, IBM, Armonk, New York). Patients were stratified into 2 frailty severity groups by baseline frailty score by the mCD-FI scale from 0 to 1:  $<0.3$  as No Frailty (NF),  $>0.3$  as Frail (F).<sup>2</sup> Patients in NF and F groups were propensity score matched (PSM) for TS-CL to control for baseline deformity. Descriptive analyses assessed clinical, surgical, demographic, and complication-related data. Frequency analysis evaluated categorical variables with chi-square analysis. Paired sample *t*-tests or Wilcoxon rank-sum tests were used to compare means from the preoperative to



3-mo and 1-yr postoperative follow-up visits. The minimally clinically important difference (MCID) for the mJOA was set at 2 based on published values.<sup>13</sup> The MCID for NDI was set as 15; this is double the published MCID value because our NDI score was collected on a 0 to 100 scale as opposed to 0 to 50). The EQ-5D MCID was set as 0.1 per previously published values.<sup>14-16</sup> Level of significance was set to  $P < .05$ .

### Development of the Normalized Integrated Health State

Normalized HRQLs (NDI, EQ5D, NRS-Neck, mJOA) were developed and analyzed allowing for the calculation of an integrated health state (IHS) with validated AUC methodology.<sup>7,8,17-19</sup> Baseline, 3-mo, and 1-yr values of each HRQL metric were divided by the corresponding baseline score within the frailty severity groups. The resulting baseline normalized HRQL score was 1 for all patients across the 2 frailty groups.<sup>19</sup> Follow-up normalized scores were either greater than, equal to, or less than 1, representing improvement or deterioration of HRQLs relative to baseline.

The normalized scores were then plotted on the y-axis of an area graph, with the x-axis representing the duration of follow up (in mo). By connecting all plotted time points, trapezoidal shapes (the change in x and y from one follow-up interval to the next) were created, corresponding to the  $\Delta x$  and  $\Delta y$  from one follow-up interval to the next. The area of each respective trapezoid was determined and summed together to create a total follow-up area. Total area (AUC) was divided by the cumulative follow-up time (52 wk for patients with complete 1-yr data). A single value (IHS) was obtained representing a patient's recovery timeline for each HRQL across the 2 frailty severity groups.<sup>19</sup> A visual representation of this process can be seen in Figure 2.

In reference to the IHS values for the HRQL outcome metrics assessed, lower NDI, NRS-Neck, and EQ5D IHS scores indicate a superior recovery process (better clinical outcomes), while a greater mJOA IHS score indicated the recovery course was better. IHS means were compared across the different categorical frailty severity (by way of the mCD-FI) states utilizing parametric and nonparametric tests as appropriate.

## RESULTS

### Cohort Characteristics Between Not Frail, Mildly Frail, and Severely Frail Patients

A total of 106 operative cervical spinal deformity patients with complete baseline, 3-mo, and 1-yr follow-up data were included, out of a total of 168 eligible operative CD patients. Mean patients age was 61.7 yr, mean body mass index (BMI) was 27.7 kg/m<sup>2</sup>, and 66% of patients were female. By categorical frailty severity, 52.8% of patients were classified as not frail, 47.2% frail. Frail patients were made up by a greater number of females, greater Charlson Comorbidity Index score, and greater incidence of smoking history when compared to NF patients ( $P < .05$ ) (Table 1). After PSM for TS-CL (mean: 38.1°), 38 patients remained in each of the NF and F groups.

### Surgical Details and Complications by Baseline Frailty Severity

By surgical approach, 46.1% underwent posterior approach, 19.7% anterior, and 34.2% combined; which was not

**TABLE 1. Basic Demographics Between Not Frail and Frail Patients in a Cohort of Cervical Deformity Patients**

	Not frail	Frail	P value
Female (%)	61%	72%	.225
Age (yr)	63.3 yr	59.9 yr	.082
BMI (kg/m <sup>2</sup> )	26.8 kg/m <sup>2</sup>	28.6 kg/m <sup>2</sup>	.135
Charlson Comorbidity Index	0.71	1.41	<b>.014</b>
History of smoking (%)	17%	48%	<b>.001</b>

Bolded cells represent statistical significance to  $P < .05$ .

**TABLE 2. Surgical Details and Mean Baseline Radiographic Parameters for Not Frail and Frail Patients in a Cohort of Cervical Deformity Patients**

	Not frail (n = 38)	Frail (n = 38)	P value
<b>Surgical descriptors</b>			
Levels fused	8.4	7.3	.650
Estimated blood loss	1171 cc	743	.239
Operative time	527 min	483 min	.228
<b>Surgical approach</b>			
Anterior only	18.4%	21.1%	.773
Posterior only	47.4%	44.7%	.818
Combined	34.2%	34.2%	1.000
<b>Osteotomy use</b>			
Partial facet	7.9%	10.5%	.692
Complete facet	5.3%	5.3%	1.000
SPO	2.6%	0.0%	.314
PSO	23.7%	0.0%	<b>.001</b>
VCR	2.6%	5.3%	.556
<b>Radiographic parameters</b>			
PT (°)	19.6	19.5	.987
PI-LL (°)	−3.1	4.7	.073
SVA (mm)	−26.5	15.2	<b>.007</b>
T4-T12 TK (°)	−43.1	−35.9	.073
T1 Slope (°)	31.6	30.2	.762
TS-CL (°)	36.7	39.6	.544
C2-C7 CL °	−5.2	−9.7	.399
C2-C7 SVA (mm)	50.0	43.0	.231
C2-T3 (°)	−18.8	−17.8	.863
CBVA (°)	7.1	5.8	.772

Bolded cells represent statistical significance to  $P < .05$ . PT = pelvic tilt; PI-LL = spino-pelvic mismatch; SVA = sagittal vertical axis; TK = thoracic kyphosis; TS-CL = T1 slope minus cervical lordosis; CBVA = chin to brow vertical angle, SPO = Smith-Peterson osteotomy; PSO = pedicle subtraction osteotomy, VCR = vertebral column resection.

significant between the frailty groups ( $P > .05$ ). NF and F had similar average number of levels fused, total operative time, and estimated blood loss (Table 2). Revision rates were similar across frailty (NF: 33.3%, MF: 26%, SF: 28.6%;  $P = .616$ ). F patients had more postop major complications (31.3%) compared to the NF (8.9%),  $P = .004$ , though DJK occurrence and reoperation between the groups was not significant ( $P > .050$ ).

**TABLE 3. Baseline and 1Y HRQL Scores for Not Frail and Frail Patients in a Cohort of Cervical Deformity Patients**

	Not frail (n = 38)	Frail (n = 38)	P value
<b>Baseline</b>			
NDI	36.8	55.4	<b>&lt;.001</b>
mJOA	14.7	12.7	<b>.002</b>
EQ5D	0.78	0.70	<b>&lt;.001</b>
<b>1Y postop</b>			
NDI	27.9	42.6	<b>.001</b>
mJOA	15.3	13.5	<b>.007</b>
EQ5D	0.82	0.76	<b>.006</b>

Bolded cells represent statistical significance to  $P < .05$ .

### Sagittal Alignment Parameters by BL Frailty Severity

At baseline, cervical and spinopelvic radiographic parameters were not significant, except for the C7-S1 SVA (NF: −26.5 mm vs F: 15.2 mm,  $P = .007$ ) (Table 2). Following corrective surgery, no significant differences were observed between frailty severity groups at 3-mo and 1-yr follow up ( $P > .05$ ).

### Standard and Normalized HRQL Analysis

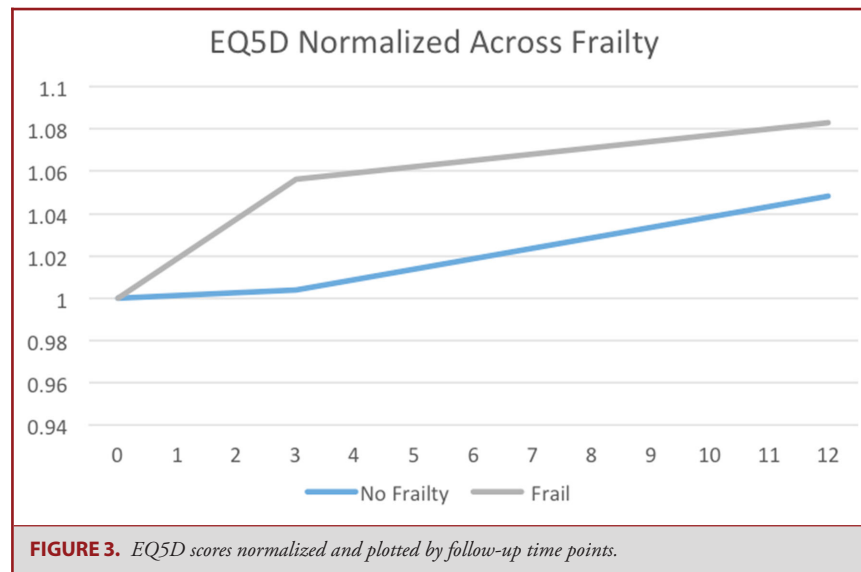
When assessing standard HRQL scores at baseline, NDI (NF: 36.8, F: 55.4;  $P < .001$ ), mJOA (NF: 14.7, F: 12.7;  $P = .002$ ), and EQ5D (NF: 0.78, F: 0.70;  $P < .001$ ) scores worsened with increasing severity of frailty (Table 3). All frailty groups exhibited BL to 1Y improvement in NDI, EQ5D, and NRS-Neck Pain (all  $P < .001$ ). Overall, 25.0% of the PSM cohort met MCID for EQ5D at 1Y postop, 38.2% met the 1Y MCID for NDI, and 30.3% met the 1Y MCID for mJOA. Frail patients were more likely to meet MCID for mJOA (NF: 18.4%, F: 42.1%;  $P = .025$ ). After HRQL normalization, F patients had more improvement in mJOA scores at 3M ( $P = .065$ ) as well as NDI ( $P = .096$ ) and EQ5D ( $P = .016$ ).

### IHS Comparison

IHS-adjusted HRQL outcomes from BL to 1Y showed a significant difference in EQ5D scores (NF: 1.02, F: 1.07,  $P = .016$ ) (Figure 3). No significant differences were found in the IHS NDI and mJOA between frailty groups ( $P > .05$ ).

## DISCUSSION

Quantifying the postoperative recovery trajectory has been increasingly studied in the spine literature.<sup>8,19</sup> Through the use of HRQL questionnaires, normalized to the baseline scores, and plotted against follow-up time, Liu et al<sup>7</sup> developed the AUC method for recovery comparison between differing groups. With frailty widely utilized as a preoperative risk assessment, it is important to understand the recovery patterns of not frail compared to categorized frail patients.<sup>6</sup> By utilizing this methodology, to create the numerical “recovery” of a patient, otherwise



known as the IHS, the present study compared the recovery of “not frail” and “frail” patients in patients undergoing cervical deformity corrective surgery.

This study examined 106 cervical deformity patients, and categorized them by their baseline frailty status to understand their recovery patterns across the span of a year. Frailty severity has been shown to connect to poor postoperative outcomes, including morbidity and mortality, as well as discharge disposition.<sup>3,5</sup> The study exhibited this relationship as well, as patients categorized as frail had increased length of stay, estimated blood loss, and occurrence of intraoperative and postoperative complications.

Patient-reported outcomes displayed a different result, as noted by the adult spinal deformity counterpart study by Pierce et al.<sup>19</sup> They touch on that the clinical decision making has been transitioning from healthcare provider recommendation to understanding the patient perspective. With this gradual shift, HRQL questionnaires have become increasingly important in the surgical spine population.<sup>20,21</sup> In addition to this focus by surgeons, the correction of cervical malalignment is majorly corrected due to one’s symptomatic presentation, rather than solely the radiographic markers of deformity.<sup>22</sup> The frail CD patients in our cohort presented with a worse baseline quality of life assessment, which is an inherent result when assessing their overall health state due to frailty. Additionally, the standard HRQL assessment postoperatively noted worse outcomes for the frail group. Several studies have focused on the impact of baseline frailty on HRQLs after surgery, and note a similar pattern.<sup>5</sup> Frail patients in a CD population have been shown to meet MCID to a greater degree than not frail patients, despite the increased postoperative complications, signifying that satisfaction may be achieved despite medically poor outcomes. Our study found a similar trend to the ASD recovery kinetics paper, that standard HRQLs remained worse for the baseline, 3-mo, and 1-yr time points at

follow up.<sup>19</sup> However, when normalizing the follow-up scores to the baseline score, the opposite finding presented itself in the patient’s outlook on their overall quality of life. Frail patients had improved recovery patterns, as defined by the Liu methodology in EQ5D.<sup>7</sup>

The cervical-centered study indicates that expectations change with differing levels of baseline quality of life. Frail CD patients were found to be superiorly satisfied with their total health (EQ5D) improvement after surgery. As frailty increases, baseline HRQLs worsen, however, frail patients in this CD population have room for a greater recovery trajectory relative to their baseline disability.

Frailty as a risk assessment tool may be useful in terms of medical and physical outcomes, but postoperative patient satisfaction may not be captured fully through one’s baseline physiological age. With additional deformity of the cervical spine (cSVA), frail patients were found to have increased hospital length of stay and medical complications. Surgeons should consider the increased risk for poor outcomes through frailty scores, but understand that frail cervical deformity patients may benefit from the patient’s point of view on their perception of their health.

### Limitations

There are several potential limitations to this study, including the inability to stratify the patients into not frail, mildly frail, and severely frail and low power due to our small sample size. The AUC methodology assumes that recovery between time points is linear, biasing the data analysis by neglecting baseline differences in HRQL scores. By normalizing the patient-reported scores at baseline, patient’s worse baseline scores are at baseline and are not accounted for, which can misguide the observation of a patient’s quality of recovery. Also, the normalization of HRQL scores at baseline only controls for baseline severity score, not other factors

contributing to heterogeneity across frailty groups. Selection bias may also play a role since frail patients may be less likely to return for follow-up medical care or evaluation.

## CONCLUSION

While all groups exhibited improved postop disability and pain scores, frail patients experienced a greater amount of improvement in overall health state compared to baseline disability. Despite frail patients having more complications, they seem to have overall better patient-reported outcomes, signifying that with frailty severity, patients have more room for improvement postop compared to baseline quality of life.

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