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Minimal early functional gains after operative treatment of midshaft clavicular fractures: a meta-analysis of 10 randomized controlled trials including 1333 patients

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Background: There is substantial evidence that operative treatment reduces the risk of nonunion but offers no long-term functional gains compared with nonoperative treatment. Despite some studies citing quicker recovery with surgery, the promise of accelerated functional recovery remains under-investigated. The aim of this meta-analysis of randomized controlled trials was to investigate the possible early functional gains (≤6 months) after operative treatment of displaced midshaft clavicular fractures compared with nonsurgical treatment.
Methods: A systematic search was performed to identify randomized controlled trials comparing plate osteosynthesis with nonoperative treatment. We evaluated shoulder function outcomes measured by Constant Score or Disability of the Arm, Shoulder, and Hand (DASH) questionnaire. Other outcomes of interest were sick leave and return to previous activity (work, leisure).
Results: Ten studies including 1333 patients were included. The mean difference in DASH score after 6 weeks was 9.4 points (95% confidence interval [CI] 13.7-5.1) in favor of operative treatment. At 3 months, the difference was 3.6 points (95% CI 6.9-0.4), and at 6 months, the difference was 3.2 points (95% CI 5.2-1.1), both in favor of operative treatment. Results for Constant Score were similar to that of DASH score.
Conclusion: This meta-analysis shows that there is an early functional gain at six weeks following plate fixation of midshaft clavicular fractures compared with nonoperative treatment. At three and six months, the functional gain is lesser and not clinically relevant.

Fractures of clavicle are common injuries with fractures of middle part accounting for more than two-thirds of all clavicular fractures.[11,16] Many patients are males and/or relatively young with an active lifestyle; patients who usually desire a fast and full recovery.[16] Traditionally, midshaft fractures have been treated nonoperatively, but the fractures are often displaced, and the incidence of operative stabilization has increased over the last decades.[14]

There is substantial evidence that operative treatment reduces the risk of nonunion, but the summarized data from randomized studies have failed to demonstrate long-term functional gains compared with nonoperative treatment.[18,41] A 2019 Cochrane review[18] concluded, “*Treatment options must be chosen on an individual patient basis, after careful consideration of the relative benefits and harms of each intervention and of patient preferences.*” While some studies highlight the potential advantage of faster functional recovery as a benefit of operative treatment,[1,19,26] the actual promise of a more rapid functional recovery has not been extensively investigated.

Different from a standard metanalysis, which customarily focus on endpoints, the aim of this meta-analysis of randomized controlled trials was to investigate the possible early functional gains (≤6 months) after operative treatment of displaced midshaft clavicular fractures compared with nonsurgical treatment. The knowledge gained from investigating early functional outcome has the potential to influence clinical decision-making. Our null hypothesis was that operative treatment of midshaft clavicular fractures yields no changes in early functional outcome scores.

Materials and methods

This meta-analysis was conducted following the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions[37] and reported according to the PRISMA recommendations (Preferred Reporting Items for Systematic Reviews and Meta-

Institutional review board approval was not required for this meta-analysis.

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Analyses)[21] (Supplementary Appendix S1). The study protocol was prospectively registered in the International Prospective Register of Systematic Reviews (PROSPERO) registry (ID: CRD42021233428).

Data sources and search strategy

A systematic search was performed on February 11, 2021, based on a search strategy developed in cooperation with a librarian from the medical library at Aalborg University Hospital. The search was updated on October 4, 2023. Searches were performed in PubMed, Embase, Cochrane Library, and Web of Science. The search strategy included subject headings and text words related to the eligibility criteria. Only studies with full-text articles available in English were included (Supplementary Appendix S2).

Study selection

Search results from all sources were imported into Mendeley (Mendeley Ltd., London). Duplicate records were deleted, and titles and abstracts were screened independently for relevance by the two authors (A.H.Q. and S.L.J.). The same two authors independently reviewed relevant full-text articles. Discrepancies were resolved by discussion until consensus was reached. Reference lists of included randomized trials were manually searched for additional eligible studies. Only truly randomized trials were included. The eligibility criteria were based on the patient, intervention, comparison, outcome and sometimes time (PICOT)[36] criteria:

Population
Adults ($\geq$15 years) with acute (<15 days) displaced, middle third clavicular fractures.

Intervention
Plate osteosynthesis.

Comparator
Nonsurgical treatment.

Outcome
Shoulder function measured by Constant Score (CS)[7] or Disability of the Arm, Shoulder, and Hand (DASH) questionnaire.[13] Other outcomes of interest were sick leave and return to previous activity (work, leisure).

Time
Only studies reporting functional results within the first 6 months after patient inclusion were of interest.

Data extraction

Both authors extracted data from each included study. Information about participants (number in each group, sex, and age), intervention (plate and/or sling type), outcome measures (DASH, CS, return to work), and results were extracted from each included study. Risk of bias was assessed individually in accordance with methods recommended by the Cochrane Collaboration.[12] Disagreements were resolved by discussion until consensus was reached.

Data synthesis and analysis

R[28] and the "meta"[2] package were used for all analysis. The analysis estimated treatment effects by determining the mean difference and standard deviation for continuous variables and employing inverse variance weighting for pooling of results. Owing to an insufficient number of studies reporting DASH and CS at all follow-up points, a test for funnel plot asymmetry was not conducted.[37] All analyses leveraged a random effects model and assessed heterogeneity via the I^2 statistic. When necessary, reported functional outcome values and confidence intervals were converted to means and standard deviations using a standardized method.[37] Reported medians, interquartile ranges, and ranges were converted to means and standard deviations with the methods of Wan et al.[39] Adjustments were made to the data in one study[20] due to a CS range discrepancy, and in another[3] to address an error in reported interquartile ranges. Missing data were imputed utilizing the last observation carried forward method, and the sensitivity of this imputation was analyzed under a worst-case scenario assumption.

Results

Study selection

In total, 1324 references were identified (Fig. 1). Duplicates were removed, and 804 articles were screened based on the title and abstract. Seventeen articles were preliminary and considered eligible for inclusion. Four of these were not randomized studies,[8,15,17,22] two did not report early functional outcomes,[4,29] and one was not in English.[9] Thus, 10 studies were included in the meta-analysis.[1,3,5,20,26,32,33,35,38,42] A manual review of the reference lists of the included studies yielded no additional references.

General study characteristics

The ten selected studies included a total of 1333 patients, of which 668 had been treated operatively. Table I shows the characteristics of each study. All fractures were characterized as displaced, using either an established classification system or by defining no contact between the fracture ends. Surgical treatment included different types of plates; most often precontoured locking plates. The postoperative regimen was usually identical for operated and nonoperated patients, but in three studies, the immobilization period was shorter or less restricted for the operated patients.[5,20,35] All studies included either DASH or CS at 6 weeks, 3 months, and/or 6 months. Three studies reported time until return to work, sports, or usual activity.[20,32,35]

Critical outcomes

The mean difference in DASH score after 6 weeks was 9.4 points (95% CI 13.7-5.1) in favor of operative treatment (Fig. 2). At 3 months, the difference was 3.6 points (95% CI 6.9-0.4), and at 6 months, the difference was 3.2 points (95% CI 5.2-1.1), both in favor of operative treatment (Figs. 3 and 4). Results for CS were similar to that of DASH score (Supplementary Appendix S3). A sensitivity analysis of our imputation method showed no difference in results between the last observation carried forward method and the worst-case drop-out scenario (Supplementary Appendix S4).

Other outcomes

Robinson et al[32] found no significant difference in time to return to work between operatively (22 days) and nonoperatively treated patients (24 days). Neither was there any difference regarding time to return to sports or number of patients returning to sports. Tamaoki et al[35] found a shorter, but statistically insignificant, time to return to work for operated patients (112 vs. 127 days). In contrast, Melean et al[20] reported a significantly shorter time to complete return to work for operated patients (3 months vs. 4 months).

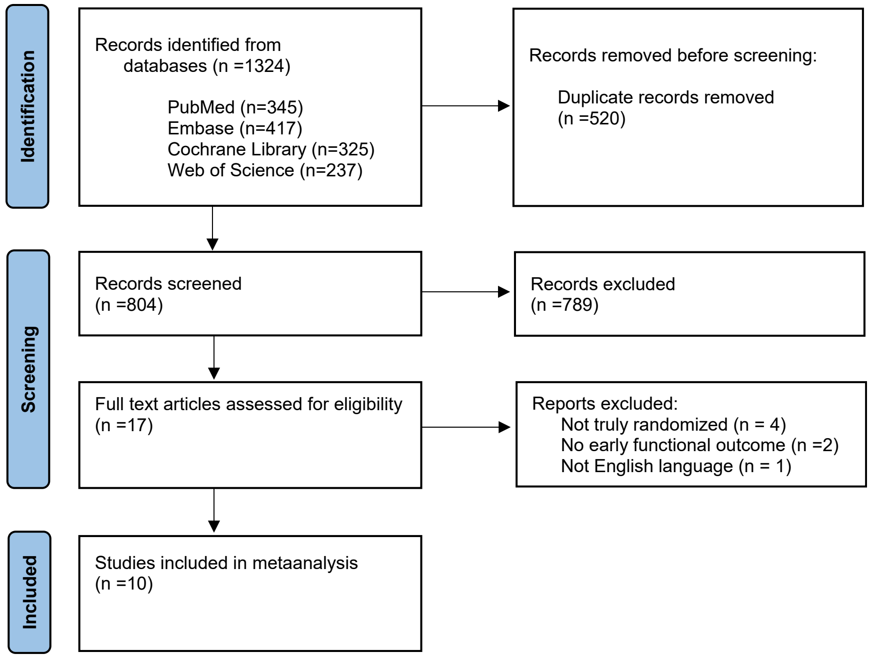

Figure 1 PRISMA flow diagram. *PRISMA*, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

Risk of bias assessment of individual studies

Risk of bias assessment is summarized in Table II. One study did not provide sufficient information to permit judgment about random sequence generation[20] and one study did merely mention that the study was randomized.[33] In three studies, the concealment method was unclear.[32,33,42] In one study, the envelopes, which were not described as sealed or opaque, were handed over to the patient, giving reason to suspect concealment was insufficient.[20]

None of the studies used sham surgery; therefore, participants were not blinded to treatment.

Likewise, since DASH is entirely and CS partly self-reported, assessment was not blinded regarding the primary outcomes selected for this meta-analysis.

Five studies were regarded at low risk of bias due to incomplete data, because participants lost to follow-up within 6 months were small or considered equal. In the other five, the numbers lost at 6 months in each group were unclear.

Five studies had a prepublished protocol with outcomes reported and measured accordingly, indicating a low risk of selective reporting.[1,3,26,38,42] In the other five studies, the risk was unclear; either the protocol had not been published or it was not retrievable.[5,20,32,33,35]

We regarded three studies at high risk of other bias because of differences in rehabilitation protocols between the groups.[5,20,35] In addition, one study did not provide baseline data to judge if the groups were balanced.[33]

Discussion

The aim of this meta-analysis of randomized controlled trials was to investigate the possible early functional gains ($\leq$6 months) after operative treatment of displaced midshaft clavicular fractures compared with nonsurgical treatment.

We found that the DASH score at all timepoints (6 weeks, 3 months, and 6 months) was better for operatively treated patients. The difference was highest at 6 weeks and became lesser thereafter. The difference at 6 weeks was 9.4 points, which is slightly lower than the reported minimal clinically important difference (MCID) of 10 points.[34] The 95% confidence interval (5.1-13.7) indicates that the real difference may be higher but also lower. Thus, it is uncertain if the difference at 6 weeks would be perceived by the patient as beneficial. At 3 and 6 months, the difference is clearly lower than the MCID. Likewise, the CS was 7.4 points (95% CI 1.8-13.0) better for operatively treated patients at 6 weeks, and lesser thereafter. At 8.3 points, the MCID for CS[10] was within the confidence intervals of our findings at 6 weeks. We expected to find similar results for DASH and CS, as the correlation between the two scores has previously been shown to be high in patients with midshaft clavicular fractures.[27]

The continued decrease after 6 weeks may suggest that the difference in functional outcome in favor of operative treatment may be higher before that timepoint. Two studies reported the collection of functional outcome data earlier than 6 weeks but did not publish the results.[32,33]

Three of the ten studies measured outcome in terms of actual function in relation to usual activities, but with conflicting results. Two studies found no difference regarding return to work or sports,[32,35] while one reported faster return to work for operated patients.[20] There was a remarkable difference in the reported sick leaves, ranging from 22-24 days in one study to 3-4 months in another. This suggests that other factors than treating the clavicular fracture operatively or not influenced the return to usual activities, for example, more or less restrictive treatment regimens.

Between studies, the treatment protocols vary between aggressive rehabilitation where all movement within pain limits are allowed from day one[26] to a more conservative approach where full range of active motion are not allowed until after six weeks and a return to full activities was restricted until three months following injury.[38] Most studies limit the use of a sling to three or four weeks, with rehabilitation exercises starting hereafter. In the context of sick leave and functional outcomes, the measured benefits of operative treatment may be diminished following more conservative rehabilitation protocols, suggesting that we may have found a greater difference in functional outcome scores had all studies used a minimally restrictive treatment regimen. The difference in rehabilitation protocols across studies may also explain some of the between-study heterogeneity

Table I
Characteristics of included studies.

	Number enrolled	Fractures included	Age range included (y)	Operative technique	Postoperative treatment	OP. number (% males)	OP. mean age (y)	Nonoperative treatment	Nonoperative number (% males)	Nonoperative mean age (y)	Functional score	Time points	Return to activity
Ahrens 2017[1]	301	Robinson 2B1 and 2B2	18-65	Precontoured locking plate	Sling for up to 6 weeks	154 (86)	36.1	Sling for up to 6 weeks	147 (88)	36.4	DASH, CS	6 week, 3 mo, 9 mo	Not reported
Ban 2021[3]	111	Robinson 2B1 and 2B2	18-65	Precontoured locking plate	Sling for up to 2 weeks	54 (84)	37.5‡	Sling for up to 2 weeks	57 (83)	39	DASH, CS	6 week, 6 mo, 12 mo	Not reported
COTS 2007[5]	132	No cortical contact between main fragments	16-60	Various plates*	Sling 7-10 d	67 (85)	33.5	Sling for up to 6 weeks	65 (69)	33.5	DASH, CS	6 week, 3 mo, 6 mo, 12 mo	Not reported
Melean 2015[20]	76	Robinson 2B1 and 2B2	Working population >18	Various plates†	Sling for 4 weeks	34 (–)	Not reported	Sling for 6 weeks	42 (–)	Not reported	CS	3 mo, 6 mo, 12 mo	Time to complete return to work
Qvist 2018[26]	146	No contact between the ends of the bone at the fracture site	18-60	Precontoured locking plate	Sling for up to 3 weeks	75 (85)	40	Sling for up to 3 weeks	71 (77)	39	DASH, CS	6 week, 3 mo, 6 mo, 12 mo	Not reported
Robinson 2013[32]	200	Robinson 2B1 and 2B2	16-60	Precontoured locking plate	Collar and cuff for 3 weeks	95 (87)	32.3	Collar and cuff for 3 weeks	105 (88)	32.5	DASH, CS, SF-12	6 week, 3 mo, 6 mo, 12 mo	Time to return to work/ sports
Shetty 2017[33]	30	Mild to moderate displaced AO type A and B midshaft fractures	20-50	Precontoured locking plate	Arm pouch for 3 weeks	16 (–)	Not reported	Arm pouch for 3 weeks	14 (–)	Not reported	DASH	6 week, 6 mo	Not reported
Tamaoki 2017[35]	117	No contact between the main fragments seen on at least 1 radiograph	"Adult patients"	3.5-mm reconstruction plate	Sling for 7-10 d	59 (90)	30.5	Figure-of-eight harness§	58 (81)	34.6	DASH	6 week, 6 mo, 12 mo	Time to return to work/ previous activities
Virtanen 2012[38]	60	No cortical contact between main fragments	18-70	3.5 mm reconstruction plate	Sling for 3 weeks	28 (86)	41	Sling for 3 weeks	32 (88)	33	DASH, CS	3 mo, 12 mo	Not reported
Woltz 2017[42]	160	Robinson 2B1 and 2B2	18-60	Precontoured locking plate in 80%	Sling for 2 weeks	86 (93)	38.3	Sling for 2 weeks	74 (89)	37.2	DASH, CS	6 week, 3 mo, 12 mo	Not reported

AO, Arbeitsgemeinschaft für Osteosynthesefragen; *CS*, Constant Score; *DASH*, Disability of the Arm, Shoulder, and Hand; *OP*, operative treatment; *SF-12*, The Short Form (12) Health Survey.
*44 patients had limited contact dynamic compression plates; 15 had 3.5-mm reconstruction plates; 4 had precontoured plates; and 4 had other plates.
†12 patients had 3.5-mm anatomic locking compression plates; 22 had reconstruction locking compression plates.
‡Median.
§Duration not reported.

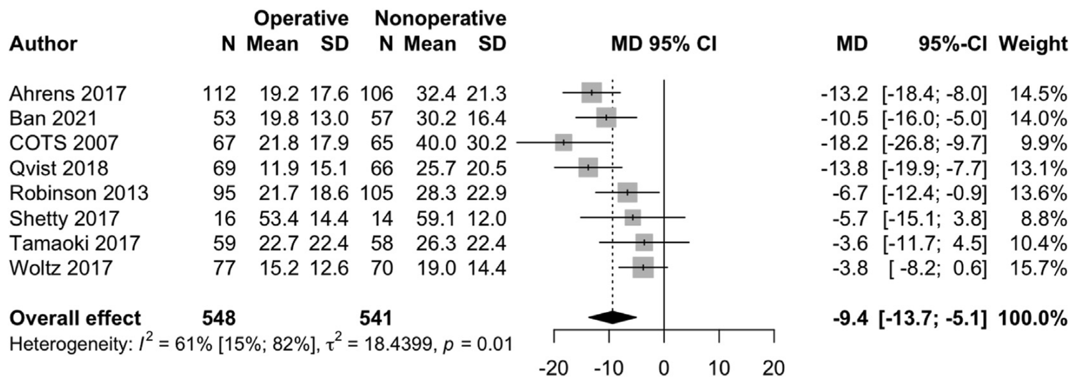

Figure 2 Forest plots, DASH 6 week. *DASH*, Disability of the Arm, Shoulder, and Hand.

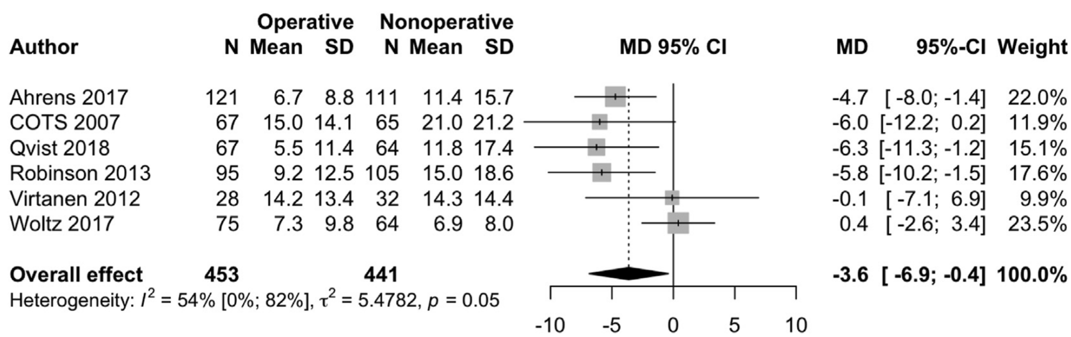

Figure 3 Forest plots, DASH 3 mo. *DASH*, Disability of the Arm, Shoulder, and Hand.

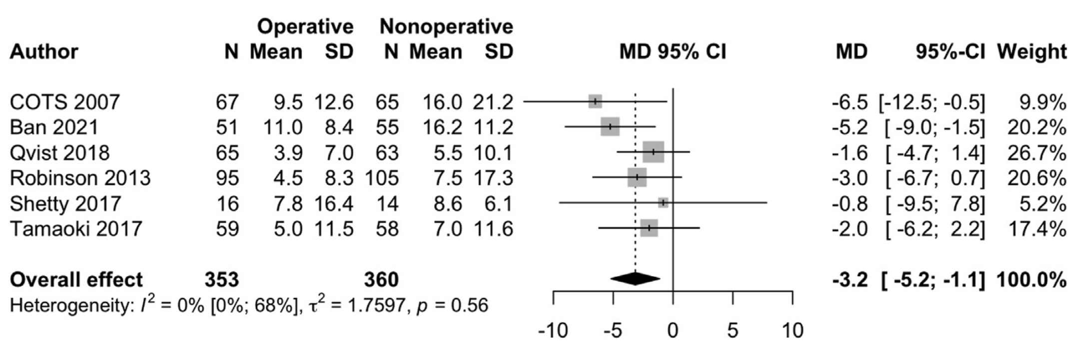

Figure 4 Forest plots, DASH 6 mo. *DASH*, Disability of the Arm, Shoulder, and Hand.

observed at six-week follow-up, since the heterogeneity in our study tends to reduce with increasing follow-up, where the difference in rehabilitation could play a lesser role.

Within studies, rehabilitation protocols are similar for operative and nonoperative treatment, except for three studies, where the nonoperative protocol was more restrictive.[5,20,35] Such a difference could tend to make a difference in early functional outcome falsely better in favor of operative treatment.

We used a random effects model for our analysis since we could not assume that the studies were performed identically. The studies vary slightly in treatment factors such as sample population, definition of displacement, rehabilitation protocols, and implants used for osteosynthesis. This means that variations between results of the included studies are not attributable to random sampling alone (as in a fixed model) but also to between study heterogeneity.[30] Using a random effects model, our estimate of the difference between the two treatments is therefore not an estimate of the true difference but rather an estimate of the mean of differences found in randomized controlled trials.

We did not have the necessary power to perform a funnel plot analysis. However, as most of the included studies reported no difference between study groups at the final follow-up,[1,3,26,33,35,38,42] we consider the risk of reporting bias to be low.

The findings in this meta-analysis add to the growing knowledge of midshaft clavicular fracture treatment and may help surgeon and patient to decide for the right treatment. For some patients, depending on physical requirements, an early functional gain, even small, may be desirable. In this context, the risks of each treatment also must be considered.

Following operative treatment of displaced midshaft clavicular fracture, the most common complications are implant related. In a meta-analysis of randomized trials, the secondary surgery rate is

Table II
Risk of bias assessment.

Study	D1	D2	D3	D4	D5	D6	D7
Ahrens 2017	+	+	X	X	+	+	+
Ban 2021	+	+	X	X	+	+	+
COTS 2007	+	+	X	X	?	?	X
Melean 2015	?	X	X	X	?	?	X
Qvist 2018	+	+	X	X	+	+	+
Robinson 2013	+	?	X	X	?	?	+
Shetty 2017	X	?	X	X	+	X	X
Tamaoki 2017	+	+	X	X	?	X	X
Virtanen 2012	+	+	X	X	?	+	+
Woltz 2017	+	?	X	X	+	+	+

Risk of bias

D1: Random sequence generation
D2: Allocation concealment
D3: Blinding of participants
D4: Blinding of outcome assessment
D5: Incomplete outcome data
D6: Selective Reporting
D7: Other Bias

Judgement
X High
+ Low
? No information

reported to be 17.6%.[36,41] Most secondary surgeries are implant removals, mostly due to implant irritation. Infection rates are lower than 10 percent, and most infections are superficial.[40,41] Brachial plexus symptoms and regional pain syndromes can be common with a reported rate of up to 38%, but these are mostly transient.[40,41] Persistent numbness of the skin is common with a reported range of 20%-70%.[26,32,42]

The main risk of nonoperative treatment is nonunion, which occurs in about 16.5 percent.[41] Symptomatic nonunions can be treated successfully in most cases, but the patient would go through a period of discomfort before the diagnosis becomes established and surgery undertaken. Prediction models, however, are available, which may help identify patients at high risk of development nonunion.[6,23,24,25,31]

Conclusion

This meta-analysis shows that there is an early functional gain at six weeks following plate fixation of midshaft clavicular fractures compared with nonoperative treatment. The gain, however, is barely clinically relevant for the average patient. At three and six months, the functional gain is lesser and not clinically relevant.

We suggest the results of the present study be considered together with other existing knowledge for an individualized treatment based on patient information and expectations.

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Supplementary Data

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