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BENCH ASSESSMENT OF A NEW INSUFFLATOR-EXSUFFLATOR DEVICE

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Véronique Porot has no conflict of interest to declare

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Abstract.

BACKGROUND. Nippy Clearway® is a new mechanical insufflator-exsufflator device used to assist cough. We assessed its capability to generate peak expiratory flow (PEF).

METHODS. Nippy Clearway® was compared to Cough Assist® in bench experiment. The relationships between PEF and pressure at the airway opening during exsufflation (Pao,exp min) were investigated under 6 different combinations of compliance (C30 or C60 ml.cmH_2O^{-1}) and resistance (R0, R05 or R20 cm$H_2O.L^{-1}.s^{-2}$) over a 25 to 50 cm H_2O range of set Pao. Intercepts and slopes of the linear regression performed over PEF and Pao, exp min relationships were compared for both devices.

RESULTS. For C30R0, C30R05 and C60R05 conditions, change in both intercepts and slopes was significant with Nippy Clearway® as compared to Cough Assist®, averaging -2.96 $L.s^{-1}$ and -0.03 $L.s^{-1}.cmH_2O.^{-2}$, -1.46 and +0.02, and -1.02 and -0.04, respectively. As a result, at any Pao, exp min, PEF was statistically significantly greater with Nippy Clearway®. For C30R20 and C60R20, regression lines were similar for all devices.

CONCLUSIONS. In the bench with Nippy Clearway® the amount of PEF was greater than with Cough Assist ® device at low respiratory system compliance.

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Introduction

Increasing cough efficacy using dedicated mechanical devices is the main therapeutic goal for with various clinical conditions with cough impairment, such as patients with chronic neuromuscular weakness [1-3] or Intensive Care Unit (ICU) patients with critical illness neuromyopathy. In France, Cough Assist® is the reference device for cough enhancement. Nippy Clearway® is a recently released mechanical insufflator-exsufflator with several new features. The aim of this study was to assess Nippy Clearway® 's performance in terms of its ability to generate significant peak expiratory flow (PEF). We selected PEF as a main end-point because it is the primary determinant of cough efficacy and, hence of airway secretion clearance. We therefore performed a bench study and compared, for each end-point, Nippy Clearway® with the corresponding reference device in this country. For this reason, we compared PEF generated with Nippy Clearway® and Cough Assist®. Our working hypothesis was that PEF would be higher with Nippy Clearway® than with the corresponding reference device used as the control due to a more advanced technology.

Material and Methods

Equipment

The set-up used comprised of the following items: 1) brand new Nippy Clearway® (B&D electromedical, Stratford-Upon-Avon, Warwickshire, UK) and Cough Assist® (Respironics France, Carquefou, France) devices fully checked by the manufacturer prior to the present investigation, 2) a two-lung configuration Test Lung (TTL, Michigan Instruments, Grand Rapids, MI, USA) with adjustable compliance (C, ml.cmH_2O^{-1}) and parabolic resistors (R) mimicking airway resistance, 3) a data acquisition system containing a pneumotachograph (Hans-Rudolph 3830/4830 series, Shawnee, Kansas) for airflow (V') measurement, a straight connector (VBM Medizintechnik GmbH, Sulz a. N., Germany) to measure pressure at the airway opening (Pao). The pneumotachograph was linear over ±10 L.s^{-1} V' range. The V' and Pao ports were connected to

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piezoresistive transducers (BD Gabarith™, Vogt Medical Vertrieb GmbH, Karlsruhe, Germany). The signals were amplified, sent to analog-digital hardware (Biopac MP150, BIOPAC Systems, Inc., Goleta, USA), and recorded at 400 Hz (Acqknowledge®, BIOPAC Systems, Inc., Goleta, USA).

Protocol

The experiment was performed over the course of one day in our laboratory, within our medical ICU, at room temperature and in room air. Before experiment, the piezoresistive transducers were calibrated before the measurements were taken, using a rotameter flow meter (Martin Médical, Lyon, France) for V' and a manometer (Fluke Electronics Corporation, Everett, WA, USA) for Pao.

The test lung was used in its single lung configuration. The device was attached to the pneumotachograph and Pao port which was connected to the test lung. Two levels of C (30 and 60 ml.cmH_2O^{-1}) and three levels of R for each of these (0, 5 and 20 cm H_2O.s.L-1) were set in the test lung in a random order. Both devices were set to automatic mode, inspiratory time 3 sec, expiratory time 1 sec, 1 sec pause after expiration.

A one-minute stabilization period was allowed for each stage after which a series of pressure pairs (positive then negative) actuated from the device was delivered. The pressures used ranged between -25/+25 cm H_2O and -50/+50 cm H_2O by steps of 5 cmH_2O for each device. For each pressure pair level, 10 consecutive breaths were recorded and the last three were retained for the analysis.

Data analysis

The experiment generated 6 CR combinations with 6 pressure pairs and 3 repetitions each making a total of 108 measurements.

The main outcome measure was PEF, taken as the lowest negative value for expiratory flow without taking into account any artifacts (figure 1). We measured actual Pao and used a linear regression analysis to model the relationship of PEF to minimal expiratory Pao (Pao,exp min),

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which was the lowest negative Pao value recorded when the air was expelled from the lung (figure 1). Each mechanical condition was analyzed separately in order to test the effects of the device and the artificial airways in different mechanical conditions representing different respiratory mechanics. Each model was supplied with estimates of two parameters, intercept and slope. A reduction in slope between the devices indicates a smaller decrease in PEF for the same change in Pao,exp min. The changes in the intercepts and slopes for the device were statistically analyzed and compared with those for the reference device.

The estimates of the slopes and intercepts were expressed as the mean ± standard error. The coefficient of determination (R^2) was used in the regression analysis. The statistical analysis was carried out using R software, version 2.9.0 (R Development Core Team. R: A Language and Environment for Statistical Computing. In Vienna, Austria: R Foundation for statistical Computing; 2009). P<.05 was set as the threshold for statistical significance.

Results

For C30R0 and C30R05, the intercepts were significantly lower and slopes significantly steeper with Nippy Clearway® than with Cough Assist® (table 1). As a result, at any Pao, exp min, PEF was significantly greater, i.e. more negative, with Nippy Clearway® (figure 2). The same significant differences in intercept and slope between the two devices were found for C60R05 as for the two CR conditions above (table 1). It should be noted that at C60R05 Cough Assist® did not reach Pao,exp min values lower than 35 cm H_2O (figure 2). Consequently, PEF was not directly measured with Cough Assist® below this threshold, and hence no firm comparison could be made between the devices. The results regarding C60R0 were similar to those obtained for C30R0 and C30R05 except for a change in slope that was not, however, statistically significant (table 1). The PEF values were, however, markedly greater with Nippy Clearway® than with Cough Assist® at all the Pao,exp min investigated (figure 2). For the C30R20 condition, intercept and slope did not differ between devices (table 1) and PEF values were similar for both at any Pao,exp min (figure 2).

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Finally, for the C60R20 condition, the slope, but not the intercept, was significantly steeper with Nippy Clearway® than with Cough Assist® (table 1) resulting in a marginal and most probably clinically irrelevant difference in PEF between devices (figure 2).

Discussion

The present bench study found that PEF was greater with Nippy Clearway® than with Cough Assist®.

Cough is the main component of airway clearance[4]. Cough efficiency is related to PEF magnitude during cough (PCEF) and, hence PCEF is an objective measure of cough efficacy. In neuromuscular patients with weak cough, the removal of secretions and airway clearance are impaired. Cough efficiency must therefore be improved in these patients and this can be achieved using various methods. However, the resulting PEF differs according to the choice of method. It has been found that manually assisted PCEF values are greater than unassisted PCEF and can be further enhanced using the breath-stacking method[5] that takes advantage of the increased lung capacity to increase PCEF.

The highest PCEF values, however, have been obtained with the use of mechanical insufflation-exsufflation devices. In neuromuscular patients, Chatwin *et al.*[1] found that unassisted PCEF averaged 2.81 $L.s^{-1}$, and that PCEF reached 3.00 $L.s^{-1}$ with physiotherapy, 3.00 $L.s^{-1}$ with noninvasive ventilation, 3.92 $L.s^{-1}$ with exsufflation assistance and 4.95 $L.s^{-1}$ with insufflation-exsufflation mechanical assistance. In normal subjects in the same study[1], unassisted PCEF averaged 9.63 $L.s^{-1}$ and significantly increased to 10.48 $L.s^{-1}$ with insufflation-exsufflation mechanical assistance. It is important to have these figures in mind for a number of different reasons. Firstly, they provide a basis for defining a PCEF threshold in order to define the starting point for using cough assistance. Secondly, they inform the clinician/researcher about which flow meter should be used to obtain an accurate measurement as the flow meter's range of accuracy needs to match the PEF range investigated. Thirdly, they help to quantify the efficacy of the various interventions made to improve cough efficiency and, hence to select the best one.

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Table 2 provides PEF values computed using the mean values of intercepts and slopes in table 1 and figure 2 for Pao,exp min equal to - 40 cm H_2O. This table shows that both devices are very sensitive to high resistance as PEF markedly decreased at R 20 $cmH_2O.s.L^{-1}$. At this high level of resistance, Nippy Clearway® and Cough Assist® exhibited virtually the same PEF-Pao,exp min relationships (figure 3). Nippy Clearway® was superior to Cough Assist® in terms of PEF under low respiratory system compliance and resistance. In a previous bench study[6], we measured the PEF generated with Cough Assist® using a similar set-up. Compared to the results of this previous study, the present PEF values are 0.60 $L.sec^{-1}$greater. It is likely that this difference comes from the use of a different device.

The difference in PEF between Nippy Clearway® and Cough Assist® devices at low respiratory system compliance and resistance can be explained by their technological features. The turbine that equips Cough Assist® works as an open circuit and there is a certain time lag for the power to reach the set pressure. In contrast, Nippy Clearway® works as a closed circuit and is under pressure as soon as the machine is turned on. Pressure is delivered from the turbine by opening a valve. As seen in figure 1, the shape of Pao inflation is quite different between the two devices: it increases abruptly and then remains constant with Nippy Clearway® but increases progressively with Cough Assist®. Therefore, with the former the set pressure is reached from the onset of inflation and maintained at that level whilst with the latter set pressure is reached at the very end. For a higher set pressure the flow increases with both devices. The flow increases further to overcome the increased resistance added to the set-up. The set pressure is reached with Nippy Clearway® but may not be achieved with Cough Assist®. In a previous study[7], we found that the Alpha 200® adapted to higher set pressure and/or increased resistance by increasing the inflation time to reach the set pressure. Finally the fact that the two devices in the present study exhibited close PEF-Pao,exp min relationships at the highest resistance (R20) highlights the limitations of the power of the Nippy Clearway® device.

Clinical implications

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In neuromuscular patients who received invasive mechanical ventilation and failed a spontaneous breathing trial[8], a value of assisted PCEF of 2.66 $L.s^{-1}$ or higher while intubated was associated with a 100% success rate for extubation. It should be noted that the post-extubation process in those unweanable neuromuscular patients included aggressive noninvasive ventilation and mechanical cough assistance. However, a similar PCEF threshold predicted successful extubation for neuromuscular patients in a previous study from the same group[9].

From the data found by Chatwin *et al.*[1], respiratory system compliance can be estimated at 35 $ml.cmH_2O^{-1}$ across all patients. Comparing the PEF values found by Chatwin *et al.*[1] and those found in the present study for similar respiratory system compliance showed that Nippy Clearway® can improve airway clearance if the resistance of the respiratory system is nil.

It should also be noted that, in addition to its effect on PCEF, the insufflation-exsufflation device used for cough enhancement shortened the duration of the airway clearance session[2], which is a significant benefit in terms of patient quality of life.

However, abruptly increasing PEF may be disadvantageous for patients with chronic airflow obstruction and lower lung elastic recoil. Mucus clearance measured by using radioactive tracers increased significantly during forced expirations and coughing in the patients with chronic bronchitis but not in those with emphysema[10].

Study limitations

The main limitation of the present study is that it is an in vitro study. The present results cannot be extrapolated to in vivo condition. However, the present results should encourage in vivo investigations to be carried out with Nippy Clearway®. The present study used devices that are currently available on the market. Further developments in turbines and software are coming up for both devices that are likely to improve the performance for both Nippy Clearway® and Cough Assist® in the near future.

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In conclusion, this bench study has shown that with the Nippy Clearway® device the amount of PEF was greater than that generated by the Cough Assist ® device at low respiratory system compliance. Clinical investigations using this new device are required.

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Figure Legends.

Figure 1. Records of flow and pressure at the airway opening (Pao) against time during the C30R05 experiment for each device. The broken vertical lines together with the thin horizontal arrows indicate the points at which peak expiratory flow and minimal expiratory pressure values were measured. The wide vertical arrow indicates the direction of inspiration.

Figure 2. Relationships of peak expiratory flow (Peak flow exp) and pressure at the airway opening during exsufflation (Pao,exp min) for Cough Assist® (closed circles) and Nippy Clearway® (open circles) at C30 (left panels) and C60 (right panels) for R0, 05 and 20 from top to bottom. Lines are regression lines. The linear regression equations are for the Cough Assist®, which is the reference device.** $P < 0.01$ vs. 0 for intercept and slopes † $P < 0.05$ vs 0. for intercept

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Table 1. Change in intercepts and slopes of the linear regression analysis for Nippy Clearway® from the reference Cough Assist® between peak expiratory flow and pressure at the airway opening for the six compliance and resistance combinations tested

	Change in intercept ($L.s^{-1}$) at Pao,exp = 0 cm H_2O	Change in slope ($L.s^{-1}.cmH_2O.^{-2}$)
C30R0	2.96 (0.13) ††	0.03 (0.004) ††
C30R05	-1.46 (0.22) ††	0.02 (0.008) †
C30R20	-0.34 (0.35)	-0.005 (0.01)
C60R0	-1.83 (0.28) ††	0.002 (0.008)
C60R05	-1.02 (0.27) ††	-0.04 (0.01) ††
C60R20	-0.12 (0.10)	-0.01 (0.004) †

Values are mean (standard error)
Pao,exp = pressure at the airway opening
† P<0.05 ††P<.001 vs. reference

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Table 2. Mean values of peak expiratory flow computed from the mean values of intercepts and slopes in table 1 at maximal expiratory pressure of - 40 cmH_2O

	C30R0	C30R05	C30R20	C60R0	C60R05	C60R20
Cough Assist®	-4.35	-3.68	-2.29	-4.93	-3.95	-2.51
Nippy Clearway®	-6.11	-4.34	-2.43	-6.68	-3.37	-2.23

Values are in $L.s^{-1}$

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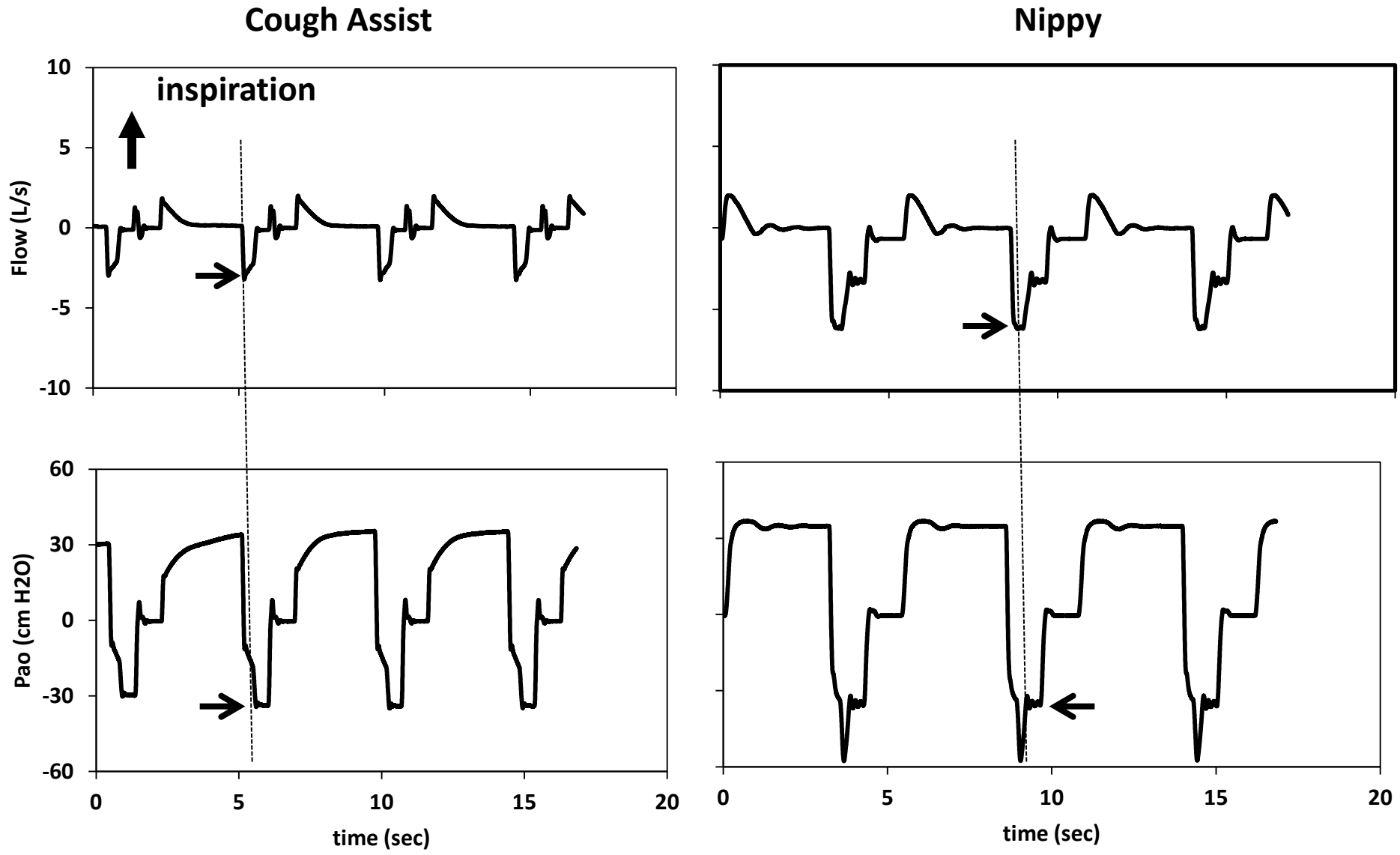

Figure 1

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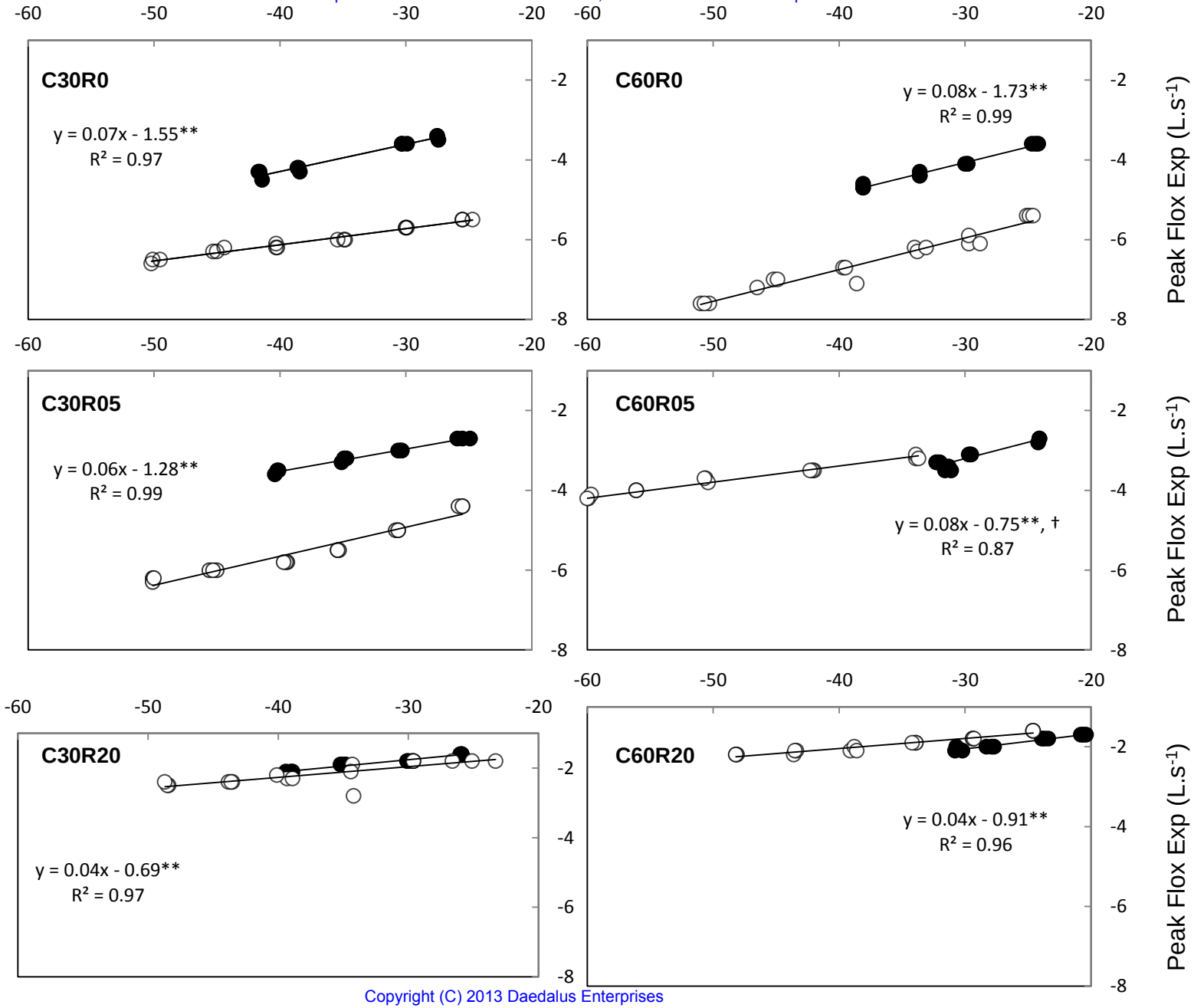

Figure 2

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