

Title:

Psychosocial Outcomes with the Omnipod® 5 Automated Insulin Delivery System in Children and Adolescents with Type 1 Diabetes and their Caregivers

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SUPPLEMENTARY MATERIAL

This supplementary material has been provided by the authors to give readers additional information about their work.

Supplement to: Hood et al. Psychosocial Outcomes with the Omnipod® 5 Automated Insulin Delivery System in Children and Adolescents with Type 1 Diabetes and their Caregivers

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Table S1. List of questionnaires for assessment of psychosocial outcomes by participant group

Questionnaire	Children	Caregivers of Children	Adolescents	Caregivers of Adolescents
PAID-C	X			
P-PAID-C		X		
PAID-T			X	
P-PAID-T				X
HCS		X	X	X
WHO-5		X	X	X
PSQI		X	X	X
IDSS		X		X
SUS		X	X	

Abbreviations: PAID-C, Problem Areas in Diabetes – Child; P-PAID-C, Parent – Problem Areas in Diabetes – Child; PAID-T, Problem Areas in Diabetes – Teen; P-PAID-T, Parent – Problem Areas in Diabetes – Teen; HCS, Hypoglycemia Confidence Scale; WHO-5, World Health Organization Well-Being Index 5; PSQI, Pittsburgh Sleep Quality Index; IDSS, Insulin Delivery System Satisfaction; SUS, System Usability Scale

Table S2. Comparison of differences in psychosocial outcomes for children and their caregivers between prior standard therapies (MDI, tubed pump, or tubeless pump)

Question- naire	MDI		Tubed		Tubeless		Mean Differ- ence ± SEM (Tubeless - MDI)	P- value [‡]	Mean Differ- ence ± SEM (Tubed - MDI)	P- value [‡]	Mean Differ- ence ± SEM (Tubed - Tubeless)	P- value [‡]
	N	Mean Change [†]	N	Mean Change [†]	N	Mean Change [†]						
<u>Children</u>												
PAID-C	7	-0.4	15	-1.5	53	-4.1***	-3.6 ± 3.5	0.3024	-1.0 ± 4.1	0.8007	2.6 ± 2.1	0.2320
<u>Caregivers of Children</u>												
P-PAID-C	7	-10.6	14	-8.9**	55	-5.2**	5.4 ± 5.1	0.2910	1.7 ± 5.1	0.7394	-3.7 ± 3.6	0.3123
HCS	8	0.28	15	0.26	58	0.23***	-0.05 ± 0.22	0.8111	-0.02 ± 0.20	0.9145	0.03 ± 0.17	0.8521
WHO-5	8	10.0	14	-3.1	59	6.2*	-3.8 ± 7.0	0.5938	-13.1 ± 8.7	0.1476	-9.4 ± 5.1	0.0702
PSQI	3	4.67	11	0.45	47	-1.40**	-6.07 ± 2.20	0.0081	-4.21 ± 2.09	0.0667	1.86 ± 1.14	0.1084
IDSS	8	0.64	15	0.79***	59	0.19*	-0.45 ± 0.23	0.0494	0.15 ± 0.31	0.6461	0.60 ± 0.17	0.0009
SUS	7	31.4*	14	22.5**	57	6.3**	-25.1 ± 6.3	0.0002	-8.9 ± 9.9	0.3790	16.2 ± 5.1	0.0021

*p<0.05, **p<0.01, ***p<0.001

[†] Change is calculated as follow-up after 3 months of AID minus baseline score

[‡] Difference between indicated groups by two-sided t-test

Abbreviations: MDI, multiple daily injections; SEM, standard error of the mean; PAID-C, Problem Areas in Diabetes – Child; P-PAID-C, Parent – Problem Areas in Diabetes – Child; HCS, Hypoglycemia Confidence Scale; WHO-5, World Health Organization Well-Being Index 5; PSQI, Pittsburgh Sleep Quality Index; IDSS, Insulin Delivery System Satisfaction; SUS, System Usability Scale

Table S3. Comparison of differences in psychosocial outcomes for adolescents and their caregivers between prior standard therapies (MDI, tubed pump, or tubeless pump)

Question- naire	MDI		Tubed		Tubeless		Mean Differ- ence ± SEM (Tubeless - MDI)	P- value [‡]	Mean Differ- ence ± SEM (Tubed - MDI)	P- value [‡]	Mean Differ- ence ± SEM (Tubed - Tubeless)	P- value [‡]
	N	Mean Change [†]	N	Mean Change [†]	N	Mean Change [†]						
<u>Adolescents</u>												
PAID-T	7	0.0	7	-3.7	24	-4.3	-4.3 ± 4.6	0.3522	-3.7 ± 4.9	0.4607	0.6 ± 4.5	0.8910
HCS	7	0.13	7	0.38	28	0.07	-0.07 ± 0.17	0.6974	0.25 ± 0.30	0.4258	0.31 ± 0.16	0.0534
WHO-5	7	0.6	6	2.7	27	4.0*	3.4 ± 5.0	0.4970	2.1 ± 9.4	0.8277	-1.3 ± 4.6	0.7750
PSQI	5	-1.80	6	0.17	14	-0.71	1.09 ± 1.49	0.4771	1.97 ± 1.39	0.1916	0.88 ± 1.18	0.4658
SUS	6	22.1*	7	26.4	27	-1.5	-23.6 ± 9.2	0.0151	4.3 ± 10.3	0.6811	27.9 ± 9.3	0.0052
<u>Caregivers of Adolescents</u>												
P-PAID-T	7	0.0	5	-12.2	23	-8.0**	-8.0 ± 4.5	0.0852	-12.2 ± 7.8	0.1501	-4.2 ± 6.0	0.4889
HCS	7	0.16	7	0.43	28	0.03	-0.13 ± 0.23	0.5873	0.28 ± 0.28	0.3386	0.40 ± 0.24	0.1006
WHO-5	7	-3.4	7	2.9	27	4.1	7.6 ± 7.2	0.3011	6.3 ± 8.1	0.4528	-1.3 ± 7.3	0.8603
PSQI	7	0.43	7	-2.29	21	-0.52	-0.95 ± 1.02	0.3606	-2.71 ± 1.49	0.0934	-1.76 ± 1.24	0.1660
IDSS	7	0.88	7	0.16	28	0.19	-0.69 ± 0.31	0.0328	-0.72 ± 0.52	0.1940	-0.02 ± 0.25	0.9264

*p<0.05, **p<0.01, ***p<0.001

[†] Change is calculated as follow-up after 3 months of AID minus baseline score

[‡] Difference between indicated groups by two-sided t-test

Abbreviations: MDI, multiple daily injections; SEM, standard error of the mean; PAID-T, Problem Areas in Diabetes – Teen; P-PAID-T, Parent – Problem Areas in Diabetes – Teen; HCS, Hypoglycemia Confidence Scale; WHO-5, World Health Organization Well-Being Index 5; PSQI, Pittsburgh Sleep Quality Index; IDSS, Insulin Delivery System Satisfaction; SUS, System Usability Scale

Table S4. Estimated coefficients for multiple and single linear regression of change in questionnaire score among children and their caregivers[†]

	Multiple Linear Regression						Single Linear Regression	
	Baseline Score	Age (yrs)	Diabetes Duration (yrs)	Sex [‡]	Baseline/ST % TBR <70 mg/dL	Baseline/ST % TIR 70-180 mg/dL	Δ % TBR <70 mg/dL [§]	Δ % TIR 70-180 mg/dL [¶]
Children								
ΔPAID-C	0.449***	-0.051	-0.567	-1.095	-0.010	0.096	-0.101	-0.060
Caregivers of Children								
ΔP-PAID-C	0.573***	0.030	-0.708	-0.084	0.483	-0.020	-1.241	0.024
ΔHCS	-0.858***	0.005	-0.016	0.034	-0.016	0.004	-0.023	-0.007
ΔWHO-5	-0.765***	0.942	-1.049	-0.385	-0.671	0.131	-0.038	-0.377
ΔPSQI - Total	0.712***	0.175	-0.307	-1.131	0.108	0.016	-0.037	-0.063
ΔIDSS - Overall	-0.615***	-0.003	0.002	-0.069	-0.040	0.003	0.060	0.003
ΔSUS	-0.889***	1.305	-1.221	-3.743	-0.183	0.049	0.801	-0.094

Data are estimated coefficient (β), *p<0.05, **p<0.01, ***p<0.001

[†] For consistency in interpreting the regression analysis, the change for each questionnaire was calculated in such a way that a positive change indicates an improvement: baseline subtracted from follow-up for questionnaires where a higher score represents an improvement (HCS, WHO-5, IDSS, SUS), and follow-up subtracted from baseline for questionnaires where a lower score represents an improvement (PAID, PSQI).

[‡] Sex was coded such that male was set to 0 and female was set to 1.

[§] Change in percent TBR is calculated as follow-up minus baseline. A negative coefficient means that a larger (more negative) decrease in TBR was associated with a greater improvement in the questionnaire score outcome.

[¶] Change in percent TIR is calculated as follow-up minus baseline. A positive coefficient means that a greater increase in TIR was associated with a greater improvement in the questionnaire score outcome.

Abbreviations: ST, standard therapy; TBR, time below range; TIR, time in range; PAID-C, Problem Areas in Diabetes – Child; P-PAID-C, Parent – Problem Areas in Diabetes – Child; HCS, Hypoglycemia Confidence Scale; WHO-5, World Health Organization Well-Being Index 5; PSQI, Pittsburgh Sleep Quality Index; IDSS, Insulin Delivery System Satisfaction; SUS, System Usability Scale

Table S5. Estimated coefficients for multiple and single linear regression of change in questionnaire score among adolescents and their caregivers[†]

	Multiple Linear Regression						Single Linear Regression	
	Baseline Score	Age (yrs)	Diabetes Duration (yrs)	Sex [‡]	Baseline/ST % TBR <70 mg/dL	Baseline/ST % TIR 70-180 mg/dL	Δ % TBR <70 mg/dL [§]	Δ % TIR 70-180 mg/dL [¶]
<u>Adolescents</u>								
ΔPAID-T	0.459**	-1.212	0.887	-1.956	0.425	-0.031	-0.425	0.107
ΔHCS	-0.555***	-0.013	0.032	0.016	0.012	0.002	-0.008	0.002
ΔWHO-5	-0.240	-1.069	0.596	-4.135	0.266	0.019	0.396	0.015
ΔPSQI - Total	0.393	0.043	-0.118	-1.699	-0.010	0.027	0.234	-0.031
ΔSUS	-0.850***	-0.752	-0.926	-5.217	1.528	-0.142	-0.560	0.024
<u>Caregivers of Adolescents</u>								
ΔP-PAID-T	0.362*	-0.285	0.687	-0.156	0.463	-0.046	-0.733	0.050
ΔHCS	-0.685***	-0.046	0.039*	0.107	0.055*	-0.005	-0.108**	0.006
ΔWHO-5	-0.709**	-1.219	0.290	4.567	0.169	-0.073	0.234	0.312
ΔPSQI - Total	0.576**	-0.520*	0.017	-1.085	0.007	-0.044	0.135	0.077*
ΔIDSS - Overall	-0.955***	-0.016	-0.004	-0.063	0.074*	-0.006	-0.060	0.001

Data are estimated coefficient (β), *p<0.05, **p<0.01, ***p<0.001

[†] For consistency in interpreting the regression analysis, the change for each questionnaire was calculated in such a way that a positive change indicates an improvement: baseline subtracted from follow-up for questionnaires where a higher score represents an improvement (HCS, WHO-5, IDSS, SUS), and follow-up subtracted from baseline for questionnaires where a lower score represents an improvement (PAID, PSQI).

[‡] Sex was coded such that male was set to 0 and female was set to 1.

[§] Change in percent TBR is calculated as follow-up minus baseline. A negative coefficient means that a larger (more negative) decrease in TBR was associated with a greater improvement in the questionnaire score outcome.

[¶] Change in percent TIR is calculated as follow-up minus baseline. A positive coefficient means that a greater increase in TIR was associated with a greater improvement in the questionnaire score outcome.

Abbreviations: ST, standard therapy; TBR, time below range; TIR, time in range; PAID-T, Problem Areas in Diabetes – Teen; P-PAID-T, Parent – Problem Areas in Diabetes – Teen; HCS, Hypoglycemia Confidence Scale; WHO-5, World Health Organization Well-Being Index 5; PSQI, Pittsburgh Sleep Quality Index; IDSS, Insulin Delivery System Satisfaction; SUS, System Usability Scale