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REPORT

Clinical evaluation of the benefit of using the "YOMPER" medical device in manual wheelchair users

PROMOTER
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Summary

1.Introduction

Mobility is presented by WHO as an essential part of an individual's good health and in particular essential for maintaining an active life. Mobility limitations are associated with low levels of social engagement and reduced mobility decreases the chances of participating in social and cultural activities.
In Europe, around a fifth of people are expected to have some form of disability from 2020 according to estimates.
In OECD countries, there is a similarity in prevalence: 1.0% to 1.4% of the population has a severe mobility disability requiring regular assistance. This represents around 900,000 people in France, out of the approximately 12 million French people affected by a disability.
In 2005, the law of February 11, 2005 specifies that “disabled people are people who suffer in their environment, any limitation of activity or restriction of participation in life in society undergone due to a substantial, lasting or definitive deterioration in one or more physical, sensory, mental, cognitive or psychic functions, of a multiple handicap or of a disabling health disorder. "
The main principle of this law is therefore accessibility of the entire travel chain for all without exclusion. This means the desire to remove all obstacles for people whatever their disability, but also the possibility for everyone to actively participate in the life of the "city".
The manual wheelchair (MW) holds a central and growing place to provide responses to disability situations.
But if it is recognized by consensus as improving mobility, performance in daily activities and functional independence, some factors unfortunately limit its advantages such as extrinsic factors related to the environment or architecture or intrinsic limits like upper limb pain.

Between the MW and the WPE (Wheelchair powered by electric motors), propulsion assistance devices could be an effective solution.

At the request of the Acekare company, it was decided to carry out a comparative evaluation to assess the benefit of using the "YOMPER" medical device in manual wheelchair users.

Goal of the study

Evaluate the effectiveness of the "YOMPER" medical device in reducing the effort made to move, with a view to improving the range of mobility of the patient in autonomy and reducing the constraints on the joints of the upper limbs without impacting the possibilities autonomy and accessibility.

2. Material and method

2.1 Regulatory aspect

The various regulatory procedures related to the study are as follows :

- Request for authorization of clinical trial of MD from the ANSM : response of 07/31/2019 that this study involving only minimal risks and constraints, is no longer subject to authorization from the ANSM (see annex 1).

- Agreement of the Committee for the Protection of the Person, CPP West II - Angers dated 10/24/2019 (see annex 2).

- Insurance certificate to conduct the study with AXA France IARD
    - contract n ° 10506496604 valid until 12/31/2019 then extended to 10/31/2020 (see annex 3).

- CE marking declaration for the Yomper+ device (see annex 4).

2.2 Population, pathology

2.2.1 Number of subjects needed

The calculation of the number of subjects required was carried out taking as the objective an expected difference of 3 points and an estimated standard deviation of 3.3 on the primary endpoint, thus a total of 19 subjects per group (i.e. 19 subjects at total, the study being crossed) is necessary for an alpha risk of 5% and a power of 80%.

2.2.2 Inclusion and non-inclusion criteria

Inclusion criteria :

- Age greater than or equal to 18 years ;
- Person with one or more deficiencies with locomotor expression ;
- MW users for more than 6 months, who, although propelling themselves, for medical reasons need electric propulsion assistance in a context defined by references d4600, d4601, d4602 and D4608 of chapter IV MOBILITY of the ICF, namely respectively "moving around the house", "moving around buildings other than the house", "moving outside the house and other buildings" and "other specified activities relating to move to other various places " ;
- User benefiting from a health insurance system or entitled ;
- User having given free and informed consent.

Non-inclusion criteria :

- Age under 18 ;
- Weight greater than 120kg ;
- Visual or cognitive impairments preventing the use of DM and MW ;
- Incompatibility of the MD with the MW ;
- Patient not benefiting from health insurance or entitled ;
- Patient who has not given free and informed consent.

2.2.3. Summary of people included

20 patients were recruited for this study, covering a range of different pathologies and etiologies (Table 1 on page 9).

They were chosen from the population of people using manual wheelchairs whose cognitive abilities allow them to control the assisted propulsion system and who, although capable of propelling themselves, for medical reasons, need to intermittent or permanent electric propulsion assistance. The inability to exercise may be due to coronary heart disease and / or respiratory failure and / or bone and joint, neurological or muscular involvement of the upper limbs.

2.2.4 Abandonment of the study / adverse events

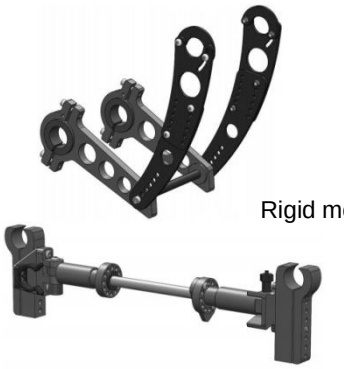
- No patient left the study
- No delay was observed in recruitment, compliance with the two-month lockdown related to COVID-19 resulted in the interruption of assessments during this period
- No incident or adverse event was observed.

2.3 Material

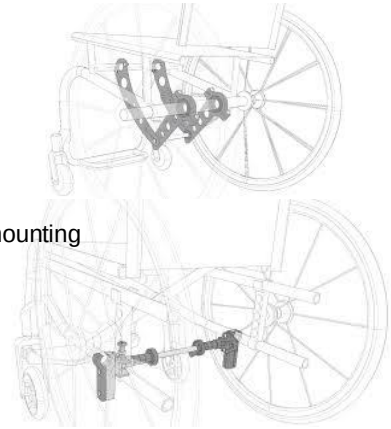
2.3.1 Material rated

The engine assistance device evaluated is Yomper+ :

This motorized wheel clips onto the frame of the patient's manual, rigid or folding wheelchair.
The assembly is done by means of a support remaining permanently on the manual wheelchair.
The motorized wheel is aligned with the axis of the rear wheels.



Rigid mounting



Foldable mounting

The control box, positioned on the patient's thigh, allows the motorization to be controlled via a Bluetooth link.

The maximum user mass is 150 kg for the motorization device (the one selected will be the lower maximum mass recommended between the device and the manual wheelchair).

The maximum speed varies between 0 and 6km/h, the patient has the choice between two driving modes (indoor indicated by green LED and outdoor indicated by red LED).

The motorization is activated by a brief double press on the control button, the wheel drives the chair without the patient having to propel the wheelchair.

A brief press on the same button cuts off the motor, the wheel is then in freewheel.

2.3.2 Wheelchair used

The manual wheelchair used with the Yomper + device is the user's usual wheelchair.

2.4 Assessment protocol

2.4.1 Study methodology

This study is prospective, single-center, open-label randomized cross-over.

It took place at CERAH, service of the National Institution of Invalids, in Woippy, from 11/04/2019 to 08/12/2020

Primary endpoint :
The main criterion for comparing the two conditions (with and without the Yomper + propulsion assistance device) is the evaluation of the perceived effort according to the BORG scale during an outdoor course of known length.

Secondary endpoints :
The secondary endpoints used are as follows :

- Evaluation of the perceived effort on the upper limbs according to the BORG scale and by measuring the number of pushes on the handrails, during the outdoor course and on certain events of the WST test ;
- Assessment of the ability to use the MW on the 22 exercises selected from the WST ;
- Evaluation of the time to complete the outdoor course ;
- Assessment of exhaustion felt in the upper limbs on a Visual Analog Scale ;
- Heart rate evaluation before and after outdoor events ;
- Assessment of satisfaction with the YOMPER medical device using the ESAT scale (QUEST), with the addition of a closed question : "Would you buy this device ?"

2.4.2 Conduct of the study

2.4.2.1 Inclusion visit
The patient is seen by one of the investigating physicians who assess the inclusion and exclusion criteria.
A pseudonymization number is assigned to it randomly.

The clinical examination and the data collected are the subject of a clinical record held by the investigating physician.
An information document on the study and its progress is explained to the patient.
If he meets the conditions for inclusion and if he gives his consent to participate, he signs an informed consent form.
The day for carrying out the tests is scheduled within about 7 days.

2.4.2.2 Conduct of practice sessions

The aim of the study is to be able to compare the performance and feelings of the patient when using their own manually-propelled wheelchair, whether or not equipped with the Yomper assistance device.

The evaluation process is described in the synopsis (cf annex 5).

The assistive device mounting kit is attached to the frame of the patient's wheelchair.

The Yomper device is put in place for explanations given by occupational therapists and takes 15 to 30 minutes.

The patient performs an exterior course (description in annex 6) and an interior course including the skills of the WST (Wheelchair Skills Test) (description in annex 7), once with the device, once without.

2.4.2.3 Assessment tools

- *The Borg 6-20 scale : it is used at the end of each of the exterior courses and after the skills of the interior course. This scale allows the patient to rate the perceived exertion from 6 to 20. The objective is to define whether the completion of the course or certain WST tests has an impact on the perceived exertion. The document used using the Borg scale is in annex 8*.

- *Heart rate : it is measured over 15 seconds before the outdoor course and immediately after the course. Before each new test, the rest period allows to return to the rest frequency*.

- The number of pushes on the handrails: counted over the entire course

- The time to complete the course

- *The Visual Analogue Scale : it is used at the end of each of the outdoor courses. This scale allows the patient to rate the fatigue felt from 1 to 5. The objective is to define whether the completion of the course has an impact on the fatigue felt in the upper limbs. (see annex 8*).

- *The Technical Assistance Satisfaction Scale (ESAT) :*

This 12-item scale makes it possible to assess overall satisfaction with the device.
It has been modified for the study (Annex 9). Indeed, we have removed the satisfaction measure concerning the services part. Under this part of the ESAT were grouped 4 items :
- the rating of procedures (allocation, time to obtain technical assistance),
- the rating of the equipment repair and maintenance service,
- the rating of the quality of professional services,
- the follow-up service rating.

These 4 items cannot be assessed by the user during this study.
We kept the first part focused on the technology aspect of the equipment classified into 8 items:

- the dimensions : concern the size of the device,
- the weight : assess when setting up, removing and lifting (transfer car),
- ease of adjustment : putting on and taking off, folding the wheelchair if possible,
- the safety aspect : sensation felt during the different routes,
- the solidity of the device : impressions,
- ease of use : in the use of the control box,
- comfort : while driving : jerks, vibrations, handling in a straight line,
- efficiency : during the course and overcome difficulties encountered on a daily basis.

It seemed relevant to us to add a section entitled **feelings** comprising 8 items :
- the feeling of freedom : when driving a wheelchair (freedom of the upper limbs),
- confidence in the system : about the responsiveness of the system,
- the ability to limit daily fatigue : felt after the outdoor course,
- the way to prevent upper limb pain,
- the possibility of increasing travel autonomy,
- ease of driving, handling,
- ease of learning,
- an overall rating.

The rating of each item is from 1 to 5 (1 corresponding to not satisfied at all to 5 very satisfied).

The questionnaire ends with the question asked to the patient whether or not he would buy the device.

3 The results

3.1 Subjects participating in the study

20 patients participated in the study between 11/04/2019 to 08/12/2020.
The population tested is made up of 7 women and 13 men. They are between 18 and 69 years old, the average age is 46 years old.
The average number of years of wheelchair use is 17 years (2 to 47 years).

Below, the characteristics of the patients recruited, the detailed description is mentioned in table 2 on page 10.

Pathologies	number
Traumatic spinal cord injuries	5
Medical spinal cord injuries	4
Motor neuron disease	3
Neurodegenerative disease	1
Polyneuropathy	3
Amputations	4
States	
Stability	11
Aggravation	9
Medical background	
No	6
Rotator cuff surgery	2
HTA	3
Diabetes NID	4
Heart disease	2
Cadiorespiratory profiles	
Asthma	3
Respiratory failure	2
RAS	15
Neuromotor profiles	
Traumatic paraplegia	3
Traumatic quadriplegia	2
Non-traumatic paraplegia	5
Upper limb pain	
Bilateral shoulders	9
Unilateral shoulders	2
Elbows	4
Handles	6
Absence	7
EVA upper limb pain (scale out of 10)	**4,8** ± 1,2 for the 20 patients
	6,1 ± 3,1 for the 13 patients reporting upper limb pain

Tableau 1 : different pathology and etiology

Table 2: detailed description of the population

Patient	Group	Gender	Age	Pathology	Associated pathology	Number of years in MW	EVA Douleur MS
5	A	M	52	low flaccid paraplegia following L1 fracture	- MI pains - operated on both shoulders following a broken headdress - left shoulder osteoarthritis	10	1
27	A	F	48	multiple sclerosis n relapsing-remitting form	cervical spondylosis and right wrist	3	2
37	B	M	31	quadriplegia C5-C6	/	12	2
26	B	M	63	double MI amputation (right transtibial and left transfemoral)	- cardiac and femoral stents - operated lumbar canal	15	3
50	A	M	66	polio sequelae (orthoses from 2 M to 11 months) rupture of the right rotator cuff	/	19	4
16	A	M	58	non-fitted transfemoral amputation	- AOMI stade IV - ischemic heart disease	20	3
11	B	F	53	MI polio = flaccid paralysis	shoulder tendinopathy	8	8
35	A	M	18	lumbar myelomeningocele = flaccid paraplegia	- equine varus foot - urinary deviation - ventricular bypass / hydrocephalus	15	6
24	A	F	34	Anterior acute polio of MI - painful right shoulder	/	19	9
29	B	M	60	quadriplegia C6C7	- cervical and scapular arthritis - Bricker	37	10
9	A	M	21	myelomeningocele	hydrocephalus derivative	18	2
42	A	M	69	paraplegia following T12-L1 fracture	- HTA - diffuse MS tendinopathies (shoulders-wrists)	47	8
21	A	M	50	paraplegia L4 / L5 (following nodules)	spasticity	5	1
36	B	F	39	IMC (genetic disease)/ paraplegia picture	- MI sensory disorders - decrease in force on the right - MS amplitude limitation - right shoulder tendonitis	20	4
40	A	M	48	paraplegia T6 / T7 following accident	very painful tendonitis left shoulder - sport: athletics	25	2
13	B	F	37	sensory disease, proprioception disorder, PIE202 **gene mutation**	- cervicalgia on arthrodesis - left shoulder tendonitis - left elbow dislocation - hyperlaxity of the fingers - need a lot of concentration in FPM because disturbed by the environment	35	7
22	B	F	34	Genetic mutation, collagen pathology	breathing difficulties	5	10
32	B	M	43	Burger's disease, double transfemoral amputation	severe pain	5	7
44	B	F	47	lumbar myelomeningocele spina bifida	- ankylosing spondylitis - pulmonary insufficiency - involvement of all MS joints	18	5
30	B	M	56	left hip disarticulation	/	2	1

*** Group** : A : starts with the Yomper device
B : starts without the Yomper device

3.2 Results inherent to the primary endpoint

Score of the effort perceived by the patient at the end of the outdoor course. The patient gives the score against the Borg scale table presented to him.

Table 3 : felt effort according to the Borg scale

Patient	Note on Borg scale **With Yomper+** (between 6 and 20)	Note on Borg scale **Without Yomper+** (between 6 and 20)	**Difference between the note without Yomper + and that with Yomper +**
5	6,5	17	**10,5**
27	6	16	**10**
37	7	14	**7**
26	6	14	**8**
50	6	15	**9**
16	9	15,5	**6,5**
11	6	11	**5**
35	6	11	**5**
24	6	15	**9**
29	6	17,5	**11,5**
9	6	15	**9**
42	9	15	**6**
21	6	14	**8**
36	7	16	**9**
40	6	14	**8**
13	6	17	**11**
22	6	18	**12**
32	6	16	**10**
44	6	14	**8**
30	6	13	**7**
Average	**6,43**	**14,90**	**8,48**
Standard deviation	0,94	1,88	2,02

3.2.1 Statistical tests :

- Kolmogorov-Smirnov normality test to verify the normality of samples :

Samples	**Calculated normality value**	**Threshold for α = 5%**	**conclusion**
With Yomper+	0,34	<0,36	We cannot reject the hypothesis that the samples are distributed according to a normal distribution
Without Yomper+	0,17	<0,36	
Difference	0,11	<0,36	

- Student's test with 19 degrees of freedom (sample size -1) to test the difference between the scores of the perceived forces with and without Yomper

Average rating **with Yomper +**	Average rating **without Yomper +**	**Average deviations (with / without)**	**P superiority**
6,43 ±0,94	**14,90** ±1,88	**8,48** ±2,02	**P<0,0001**
Confidence interval at.α =5%	Confidence interval at.α =5%	Confidence interval at.α =5%	
[6,00 ; 6,86]	[14,03 ; 15,77]	[7,54 ; 9,41]	
[min ; max] [6 ; 9]	[min ; max] [11 ; 18]		

3.2.2 Conclusion :

The average perceived effort during the outdoor course using the Borg scale (6-20) is 14.90 without the Yomper + device and 6.43 with it. The mean of the differences is 8.48 highlighting a significant difference between the 2 measurements ($p < 0.0001$).

Note that 4 patients were not able to complete the entire tour with their manual chair not equipped with the Yomper + device (severe fatigue, shoulder pain, dyspnea).

The Borg scores assigned by patients during the course with their chair without the device range from **11** (fairly easy) for 2 of them to **18** (very hard) for 2 other patients.

For the same route performed with the Yomper + device, the Borg scores assigned by the patients ranged from **6** (very very easy) for 15 of them to **9** (very easy) for one of them.

3.3 Results inherent to the secondary endpoints evaluated during the outdoor course

Tables 4 and 5: secondary endpoint

Patient	Number of pushes on the handrails			Time taken to complete the route (in s)			Exhaustion felt in the upper limbs		
	With Yomper+	Without Yomper+	Deviations	With Yomper+	Without Yomper+	Deviations	With Yomper+	Without Yomper+	Deviations
5	2	143	**141**	198	123	**-75**	1	4	**3**
27	2	204	**202**	222	225	**3**	1	4	**3**
37	4	212	**208**	208	223	**15**	1	3	**2**
26	2	313	**311**	188	315	**127**	1	2	**1**
50	2	160	**158**	172	130	**-42**	1	2	**1**
16	10	336	**326**	197	287	**90**	1	4	**3**
11	10	338	**328**	197	262	**65**	1	2	**1**
35	10	182	**172**	174	195	**21**	1	2	**1**
24	10	353	**343**	187	281	**94**	1	4	**3**
29	10	270	**260**	195	290	**95**	1	4	**3**
9	5	186	**181**	190	163	**-27**	1	3	**2**
42	5	191	**186**	172	219	**47**	1	4	**3**
21	3	341	**338**	160	264	**104**	1	4	**3**
36	4	350	**346**	157	266	**109**	1	4	**3**
40	5	172	**167**	168	188	**20**	1	4	**3**
13	1	233	**232**	175	321	**146**	1	5	**4**
22	1	415	**414**	170	227	**57**	1	5	**4**
32	2	225	**223**	176	249	**73**	1	5	**4**
44	1	230	**229**	158	298	**140**	1	3	**2**
30	1	182	**181**	170	225	**55**	1	2	**1**
Average	**4,5**	**251,8**	**247,3**	**181,7**	**237,6**	**55,9**	**1**	**3,5**	**2,5**
Standard deviation	3,5	80,4	79,7	17,5	56,9	60,9	0	1,1	1,1

Patient	Heart rate variation **with Yomper+**			Heart rate variation **without Yomper+**			**Difference on spreads with and without Yomper**
	Rest F	Frequency after run	Deviations	Rest F	Frequency after run	Deviations	
5	84	84	**0**	80	132	**52**	**52**
27	70	72	**2**	72	92	**20**	**18**
37	82	80	**-2**	88	116	**28**	**30**
26	66	68	**2**	70	100	**30**	**28**
50	82	92	**10**	80	140	**60**	**50**
16	72	73	**1**	76	105	**29**	**28**
11	84	88	**4**	84	120	**36**	**32**
35	72	76	**4**	74	108	**34**	**30**
24	80	79	**-1**	80	120	**40**	**41**
29	76	80	**4**	78	98	**20**	**16**
9	72	74	**2**	72	108	**36**	**34**
42	78	78	**0**	78	122	**44**	**44**
21	61	62	**1**	62	102	**40**	**39**
36	72	75	**3**	66	131	**65**	**62**
40	84	84	**0**	84	112	**28**	**28**
13	72	72	**0**	72	90	**18**	**18**
22	91	92	**1**	90	105	**15**	**14**
32	50	51	**1**	48	114	**66**	**65**
44	82	80	**-2**	80	130	**50**	**52**
30	76	76	**0**	72	104	**32**	**32**
Average	***/***	***/***	**1,5**	***/***	***/***	**37,2**	**35,7**
Standard deviation	/	/	2,7	/	/	15,1	14,8

Judging criteria	With Yomper +	Without Yomper +	Average deviations (with / without)	Statistical test	P superiority
Number of pushes on the handrails	**4,50** ± 3,52 [min ; max] [1 ; 10]	**251,80** ±80,42 [min ; max] [143 ; 415]	**247,30** ±79,65 Interv. of conf. α =5% [210,5 ; 284,1]	Test de student à 19 ddl	**P<0,0001**
Time to complete the route	**3min02s** ± 17s [min ; max] [2min37; 3min42s]	**3min58s** ± 57s [min ; max] [2min03s ; 5min21]	**56s** ± 60s [min ; max] [-1min15 ; 2min20]		**P<0,001**
Exhaustion felt in the upper limbs (numerical scale from 1 to 5)	**1,00** ±1,05 Interv. of conf. α =5% [1,00 ; 1,00] [min ; max] [1; 1]	**3,50** ±0,0 Interv. of conf. α =5% [3,01 ; 4,99] [min ; max] [2; 5]	**2,50** ±1,05 Interv. of conf. α =5% [2,01 ; 2,99]		**P<0,0001**
Increase in heart rate before / after ride (beats / min)	**2** ±3 [min ; max] [-2 ; 10]	**37** ±15 [min ; max] [15 ; 66]	**36** ±15		**P<0,0001**

Conclusions :

The differences are statistically significant reported on all the secondary endpoints for the outdoor course obtained with use of Yomper+ and without use of Yomper+.

The difference in the number of pushes is important, justified by the fact that it is not necessary to use the handrails to start the wheelchair equipped with the motor or to propel it. Pushes on the handrails with the Yomper + device have been counted when the user needs to give impulses to turn or keep the straight line (the majority of them prefer to brake the inside wheel when turning).

The lack or little action on the handrail automatically generates much less fatigue in the upper limbs than with the wheelchair without the Yomper device.

When carrying out the outdoor course in FRM with the Yomper + device, 100% of patients rate their perceived fatigue at 1 (“I feel rested, I am functioning well, I am in control of the situation”). Without the use of the Yomper+ device, 100% of patients rate their perceived exhaustion at more than 2, 75% of which rate it at more than 3 ("I feel moderate fatigue. I have to modify my activities (add breaks or divide my tasks) ”).

The difference in travel time is significant but less important because some patients were able to cover the distance faster without the Yomper+ than with it. Note that the maximum speed was programmed at 6 km / h and that all the patients, except one, used the outdoor mode (red LED) in its fastest mode while they had free choice of setting. The exception, level 3 or 4 of the outdoor mode, was constrained due to excessive vibration of the wheelchair's front wheels at maximum speed.

Heart rate is measured before the start of each course and immediately upon arrival. It is taken over a period of 15 seconds. The variations recorded should be compared with the rating of the perceived forces.
With the Yomper+, the perceived exertion is low, the variation related to the distance traveled is not significant (lower for some, slightly increased for others, perhaps related to the stress of driving with Yomper+).
Without the Yomper+, the frequency is on average increased by 37 beats / minute (between 15 and 66 depending on the patient).

3.4 Results inherent to the secondary endpoints assessed during the WST (Wheelchair Skills Test) indoor course

The 22 skills deemed to be the most relevant from the Wheelchair Skills Tests (WST-F, version 4.3 of January 2017) were selected for the indoor course. The description is specified in annex 7.

For the course performed without Yomper, the device is removed. For the course with Yomper, the patient has the choice of his driving program (indoor or outdoor) and whether or not to use the Yomper (the device remains in place, the motorization being in freewheel).
Each skill is scored from 0 to 2, 0 if the skill is not passed, 1 if it is passed with difficulty, and 2 if it is passed without difficulty. The score obtained is reported on the maximum score of 44 to obtain a score in the form of a percentage.

Table 6: WST secondary endpoint

Patient	Heart rate variation with Yomper+		
	WST score with Yomper+	WST score without Yomper+	Deviations
5	95,45	93,18	**2,27**
27	90,91	90,91	**0**
37	90,91	90,91	**0**
26	90,91	90,91	**0**
50	100	100	**0**
16	90,91	90,91	**0**
11	81,82	88,64	**-6,82**
35	90,91	95,45	**-4,54**
24	90,91	77,27	**13,64**
29	81,82	81,82	**0**
9	100	95,45	**4,55**
42	90,91	84,09	**6,82**
21	90,91	88,64	**2,27**
36	90,91	84,09	**6,82**
40	100	100	**0**
13	88,64	79,55	**9,09**
22	88,64	79,55	**9,09**
32	90,9	90,9	**0**
44	90,9	90,9	**0**
30	95,5	95,5	**0**
Average	**91,59**	**89,43**	**2,16**
Standard Deviation	4,99	6,57	4,86

Judgment criterion	With Yomper +	Without Yomper +	Average deviations (with / without)	Statistical test	P non-inferiority
Skills (%)	**91,59** ± 4,99 Interv. de conf. α =5% [89,33 ; 93,85]	**89,43** ±6,57 Interv. de conf. α =5% [86,40 ; 92,46]	**2,16** ±4,86	Test de student à 19 ddl	**P=0,25**

Conclusion :

The difference is not significant between the two courses, with and without Yomper +. There is therefore no non-inferiority on the criteria of skills during the WST related to the use of the Yomper+ device.

During the course with Yomper+, the majority of the patients used the motorization for all the skills with the exception of "pivoting in place : 180 ° in one direction then in the other in a square of 1.5 meters on the side" and to go up and down a difference in level (the Yomper + device is not claimed as an aid to obstacle clearance ".

Half of the patients completed the route using the outdoor driving mode.

3.5 Results of the satisfaction assessment using the ESAT scale (rated out of 5, at least to most satisfactory)

The questionnaire was completed at the end of all the tests. The patient fills in his notation alone, clarifications are provided in the event of questions.

Patient	ESAT			Would you buy the device?
	Technological subscale	Subscale felt	Total score	
5	4,75	4,875	4,122	Oui
27	4,13	4,5	4,31	Oui
37	3,88	4,13	4	Oui
26	4,5	4,38	4,44	Oui
50	4,63	4,63	4,63	Oui
16	5	5	5	Oui
11	4,5	4,75	4,625	Oui
35	4,375	4,75	4,56	Oui
24	4,75	4,875	4,813	Oui
29	4,75	4,625	4,688	Oui
9	4,25	4	4,125	Oui
42	4	4,125	4,0625	Oui
21	4,25	4,5	4,375	Oui
36	3,75	4,5	4,125	Oui
40	4,375	4,75	4,5625	Oui
13	3,625	4,75	4,1875	Oui
22	4,5	4,75	4,625	Oui
32	4,5	4,875	4,6875	Oui
44	4,375	4,625	4,5	Oui
30	4	4,375	4,1875	Non
Average	**4,345**	**4,588**	**4,431**	
Standard deviation	0,362	0,275	0,281	

Conclusion :

The scores assigned by the patients attest to the satisfaction encountered with the Yomper+ device. This opinion is reinforced by the proportion of positive response compared to the purchase.

4. Findings of the evaluation

The results show that the Yomper+ device provides users with greater propulsion and accessibility possibilities compared to their manual propulsion wheelchair.

The fact that the power supply to the motor allows the wheelchair to be propelled without action on the handrails results in reduced perceived efforts and a less feeling of fatigue in the upper limbs.

The action on the handrails is still necessary to steer the wheelchair (turn and hold in a straight line) and possibly to slow down the wheelchair..

Freewheeling the Yomper + when the engine is off allows users to use the manual wheelchair without having to remove the device. The alignment of the axis of the motorized wheel with the axle of the rear axle helps maintain the maneuverability of the wheelchair.

These relevant properties translate into a non-inferiority of the Yomper+ on the WST tests and in indoor use.

All of these possibilities and performances lead to a high overall satisfaction rating and conclude the willingness to purchase the device.

Made in Woippy, le 26/11/2020

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