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Master of Science in Biomedical Engineering

Evaluation and improvement of the embodiment of an upper limb prosthesis: the Hannes system

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Abstract

Introduction and objectives

The research activities developed at the Rehab Technologies IIT/INAIL Lab are focused on the traumatic loss of the upper-limb effector: the hand. The solution which allows to overcome this disability is the prosthesis. The prosthetic world is in continuous development: from the old solutions only allowing the restoration of the aesthetic aspect, thanks to the technological innovation, nowadays, the prostheses can assure the recovery of both the lost functionalities and aesthetics. The myoelectrically controlled poly-articulated prosthetic hands are the latest advanced devices commercially available offering these features. Nevertheless the high level of technology reached, prosthesis abandonment rate is still very high. The reason of this rejection can be found in the low level of embodiment which characterizes the prostheses. The embodiment defines the integration into the corporal (and mental) scheme of an external device, in this case the prosthesis. This thesis consists of two studies related to this phenomenon.

The first study investigated the level of embodiment reached with the novel prosthetic hand *Hannes* (developed by the Rehab Lab) through the pre-validation of an official post-market clinical trial. The ***main objectives*** were the *improvement*, through the domestic use, of the **embodiment** and the **user experience** (UX) of *Hannes* and their *evaluation* over time. The ***secondary objective*** regarded the *evaluation* of the **functionality**, aspect which indirectly influences the embodiment and that can be anyway improved in the same way through the daily use. Furthermore, a *comparison* between *Hannes* after the prolonged use and the commonly used prosthesis was conducted.

The second study regarded an exploratory activity focused on a custom-made tool for **stimulating** and **"training"** the **embodiment** of a virtual representation of *Hannes* hand. The basic assumption was that, with a *forced induction* of a *psychophysiological state* through the modulation of the *breathing*, it was possible to achieve a physical and mental condition in which the **embodiment process** was *facilitated*. Precisely, a *slow breathing rate* was supposed to better induce this state with respect to a normal one. The long term idea is to intrinsically induce the embodiment process of the real prosthesis through the virtual training with the virtual hand, since they look identical.

State of the art

The bone structure and the muscles which control the hand and the wrist allow these organs to perform several and complicated movements, in which the grasping is the most relevant. Indeed, the hand and the wrist together possess 27 DOFs[1]. The loss of a hand can be defined as a traumatic event, especially for the accomplishment of the ADLs[2]. A research conducted by the *Italian Ministry of Health* from 2006 to 2013 estimated, in Italy, about 1600 new upper limb amputations every year. The myoelectric prostheses are controlled by the contraction of residual muscles within the stump. The most used control strategy implements a proportional regulation thanks to two surface electrodes (sEMG). These sEMG detect the activity of flexor and extensor muscles to respectively close and open the prosthesis. i-Limb, Michelangelo and Bebionic hands are the main poly-articulated myoelectrically controlled prostheses currently available on the market and *Hannes* is considered equivalent to them. Indeed, the pre-market study performed on *Hannes* confirmed its usability and high efficacy in term of functionality with respect to the other commercial devices. The post-market clinical trial on which the pre-validation is based is inspired by this clinical study but the core activity is focused on the embodiment. Indeed, the embodiment has been demonstrated to promote the prosthesis control and acceptance.

Materials

Hannes is a myoelectrically controlled poly-articulated prosthetic hand which received the CE mark in 2017. It is capable to restore over 90% of lost functionality and its marketing process is under development. *Hannes* is the result of a co-development activity between researchers, patients, orthopaedists and industrial designers which allowed to make it very similar to the human hand in term of size, shape and kinematics behaviour (Figure 1).

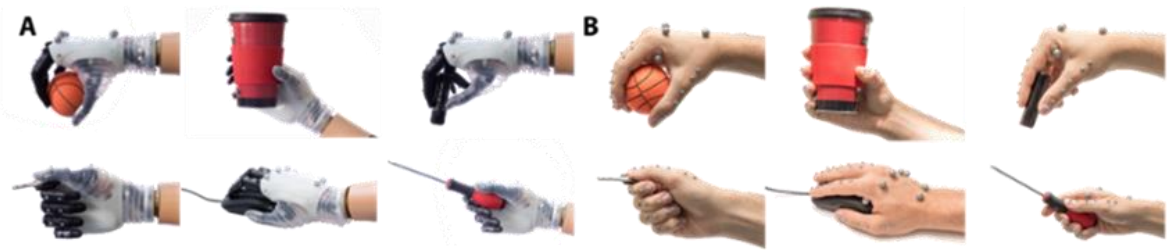


Figure 1: *The Hannes hand* ***(A)*** *in comparison with the human hand* ***(B)*** *during grasp tasks.*

The feature which makes *Hannes* unique is the innovative DAG[3] system. The embedded transmission mechanism consists of a tendon-driven differential mechanism capable to

[1] Degrees Of Freedom
[2] Activities of Daily Life
[3] Dynamic Adaptive Grasp

properly offer the patient a quick and precise grasp. This mechanism allows the prosthesis to adapt to the shape of any object and to resist to any external disturbance, giving human-like grasping properties, such as robustness, stability and synergistic coordination of the fingers.

Methods

The **pre-validation** included three pro-users of myoelectric prosthesis. They indeed were equipped with Bebionic, Variplus and Michelangelo hand respectively. The study lasted three months with regular follow-ups at the end of each month (T1 at the beginning, then T2, T3, T4) for the evaluation of the user experience, the embodiment and the functionality of *Hannes* through questionnaires and tests. Furthermore, an evaluation was also executed on the reference hand at the beginning of the study (TB) to allow the comparison. The evaluation exploited different methods, summarized in Figure 2.

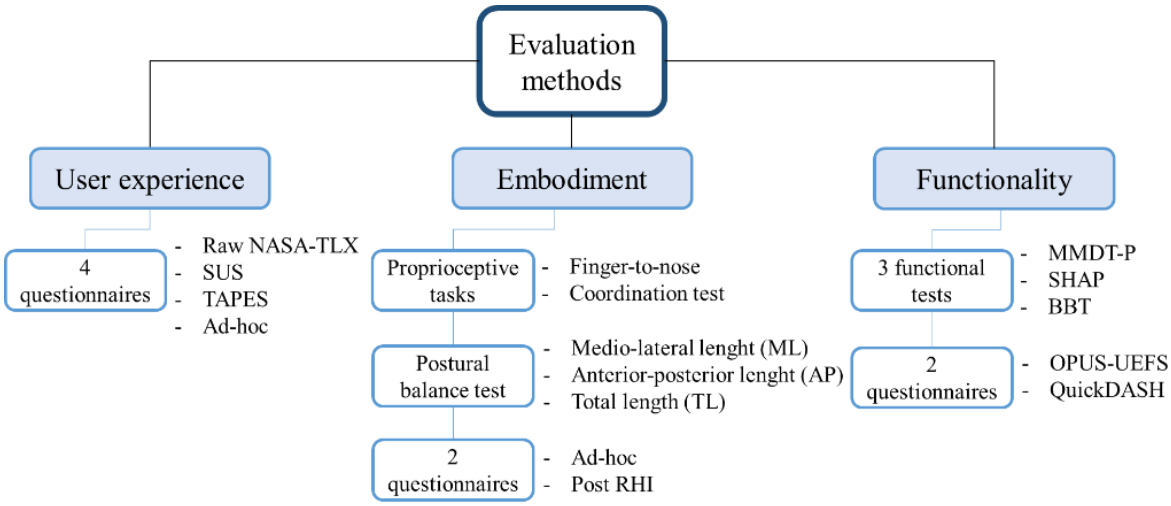


Figure 2: *Evaluation methods adopted in the pre-validation.*

Some of these methods are internationally validated: raw NASA-TLX[4], SUS[5], TAPES[6], OPUS-UEFS[7] and QuickDASH[8] as questionnaires whilst MMDT-P[9], SHAP[10] and BBT[11] as functional tests. The proprioceptive tasks and the postural balance test introduced innovative methods (Figure 3) for an objective evaluation of the level of embodiment. Moreover, two questionnaires were specifically drawn up in this clinical study for the evaluation of the embodiment and the user experience. One of them was administered after a modified session

[4] NASA Task Load Index
[5] System Usability Scale
[6] Trinity Amputation and Prosthesis Experience Scales
[7] Orthotics and Prosthetics User's Survey - Upper Extremity Functional Status Survey
[8] Disabilities of the Arm, Shoulder and Hand Score
[9] Minnesota Manual Dexterity test – Placing test
[10] Southampton Hand Assessment Procedure
[11] Box and Block Test

of Rubber Hand Illusion (RHI), used to strengthen the embodiment. In this session, vibrotactile stimuli were given to the stump simultaneously to the visual contact of an object with the prosthesis.

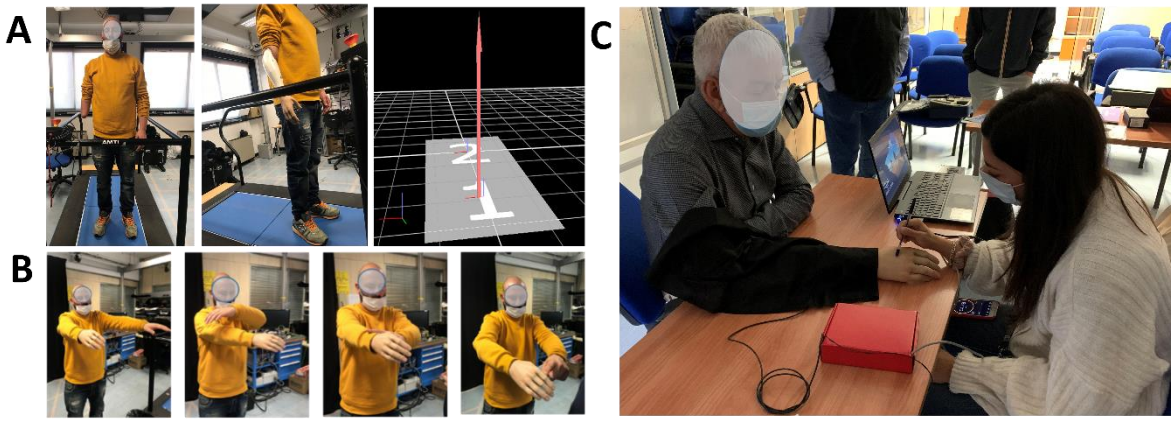


Figure 3: ***(A)*** *Postural balance test,* ***(B)*** *Proprioceptive tasks and* ***(C)*** *Modified RHI.*

The exploratory study on the **"embodiment training"** tool exploited a custom-made spatially augmented reality developed in the Unity software and a basic set up to be replicable at home. 12 healthy subjects and 2 amputees were included in this feasibility study. The participants were asked to increase the opacity of a virtual hand (a virtual 3D copy of *Hannes*) through the correct maintenance of the requested target breathing rate. This would have allowed an energetic sphere (represented as moving towards the hand in Figure 4) to trigger a visual vibration once it was under the hand. The vibration of the hand appeared in the screen while simultaneously a tactile vibration was applied to the real right hand through a smartphone placed under the real hand.

Figure 4: *Sequence of scenes during the execution of the trial.*

The task was administered (for 16 trials of 1 minute each) under two different target breathing rates:

1. A Slow Breathing (SB) rate, around 6 breaths/minute
2. A Normal Breathing (NB) rate, around 14 breaths/minute

The breaths for the elaboration of the breathing rate were detected with a microphone placed in front of the mouth (Figure 5 **A**). The evaluation of the embodiment towards the virtual

hand was performed, at the end of the experiment, with a subjective questionnaire and with the measurement of the proprioceptive drift (Figure 5 **B**).

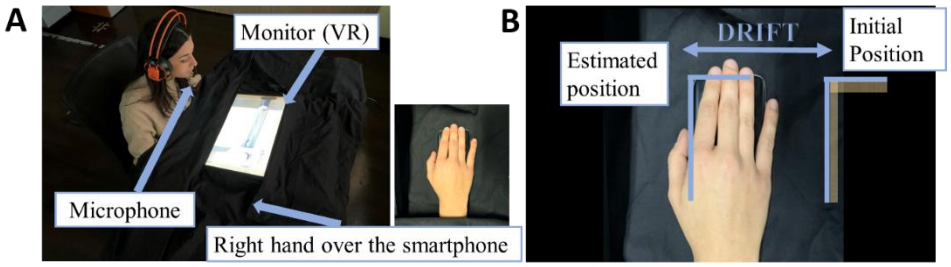


Figure 5: ***(A)*** *Set up and* ***(B)*** *Proprioceptive drift.*

Results

The **user experience** showed an improvement over time, as confirmed by the general descending trends expected in the raw NASA-TLX score and the general ascending trends expected in the overall index of the SUS and TAPES questionnaires (Figure 6).

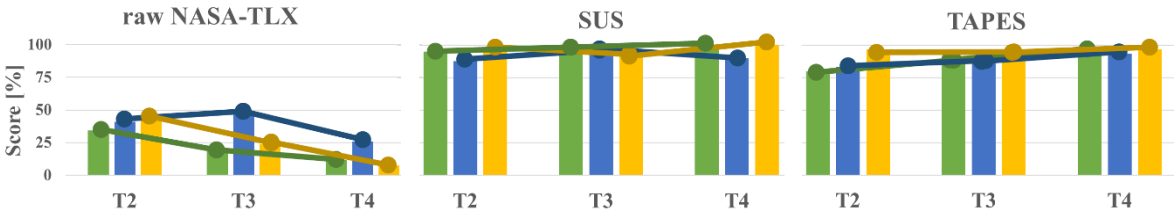


Figure 6: *User experience score results with Hannes for each time of investigation (T2, T3, T4). Green for subject 1, blue for subject 2 and yellow for subject 3.*

Also the Ad hoc questionnaire, which did not provide an overall index, showed improved scores regarding the UX over time. Overall, *Hannes* assured a better UX with respect to the commonly used prostheses, as highlighted by the improvements reported in Table 1.

Subject 1	T4-TB [%]
Raw NASA-TLX [%]	54,8
SUS [%]	42,9
TAPES [%]	31,8

Subject 2	T4-TB [%]
Raw NASA-TLX [%]	16,2
SUS [%]	2,9
TAPES [%]	15,5

Subject 3	T4-TB [%]
Raw NASA-TLX [%]	83,0
SUS [%]	33,3
TAPES [%]	0,0

Table 1: *Comparison between Hannes in T4 and the reference prosthesis in TB. Green cells for an improvement, red cells for a deterioration and yellow cells for equality.*

The **embodiment** evaluation through the Ad hoc questionnaire showed improved scores for each subject over time in the items related to this aspect. The questionnaire regarding the session of the modified RHI, as the Ad hoc questionnaire, did not provide an overall index and it was evaluated item by item. Subject 1 and 3 improved a little their scores, while subject 2 showed a slight worsening in the scores. The proprioceptive tasks showed a general trend towards the 0 deviation, which was the ideal target. Hence, the proprioceptive tests showed an improvement over time and, furthermore, improved results with *Hannes* compared to the

baseline evaluation with the reference hands. The TL[12], ML[13] and AP[14] path lengths investigated in the two conditions (eyes-opened and eyes-closed) with the postural balance test showed, as expected, descending trends over time (Figure 7).

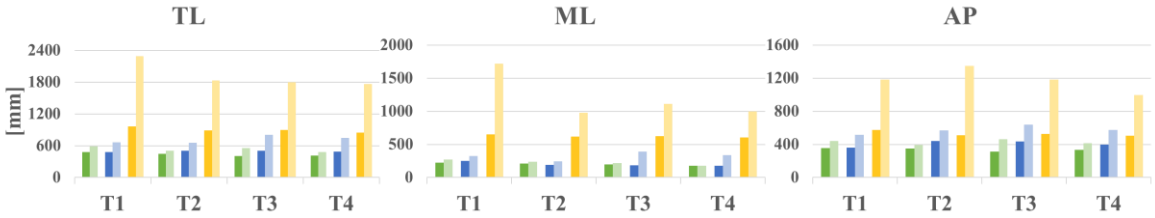


Figure 7: *Postural balance test results with Hannes for each time of investigation (T1, T2, T3, T4). Dark colours for the eyes-opened condition and light colours for the eyes-closed condition. Green for s1, blue for s2 and yellow for s3.*

The comparison between the oscillations with *Hannes* and with the commercial prostheses showed better (lower oscillations) results for *Hannes*, but the comparison between *Hannes* and the absence of prosthesis presented several deteriorations (Table 2).

Subject 1	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	15,0	-16,9
	EC	24,0	14,3
ML [mm]	EO	22,6	-8,9
	EC	37,9	28,8
AP [mm]	EO	11,3	-19,4
	EC	17,4	8,1

Subject 2	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	6,9	-30,6
	EC	14,7	-3,9
ML [mm]	EO	27,4	-11,9
	EC	18,7	-4,1
AP [mm]	EO	3,9	-29,1
	EC	16,9	1,6

Subject 3	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	22,7	20,0
	EC	13,1	1,5
ML [mm]	EO	31,2	30,8
	EC	36,4	29,4
AP [mm]	EO	-2,7	-14,6
	EC	-0,9	-16,1

Table 2: *Comparison between Hannes in T4 and the reference prosthesis in TB and the absence of prosthesis. Green cells for an improvement, red cells for a deterioration and yellow cells for equality.*

The **functionality** improved over time. This is appreciable with a descending trend in the MMDT-P test and ascending trends in both SHAP IoF[15] and BBT test (Figure 8).

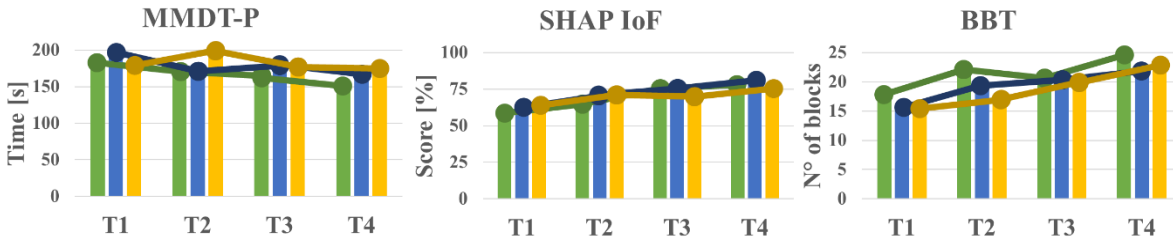


Figure 8: *Functional tests results with Hannes for each time of investigation (T1, T2, T3, T4). Green for subject 1, blue for subject 2 and yellow for subject 3.*

The improved efficacy in the ADLs is showed over time by the descending trend of the QuickDASH total score (except for subject 1) and the ascending trend of the percentage of usage calculated with the OPUS-UEFS (except for subject 3) (Figure 9).

[12] Total
[13] Medio-Lateral
[14] Anterior-Posterior
[15] Index of Functionality

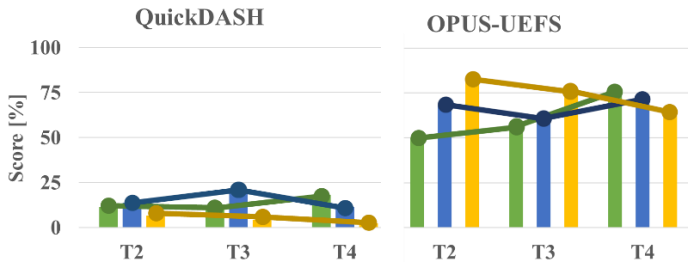


Figure 9: *Functional questionnaires results with Hannes for each time of investigation (T2, T3, T4). Green for subject 1, blue for subject 2 and yellow for subject 3.*

In general, at the end of the study (T4) *Hannes* improved functionality with compared to the reference prostheses evaluated in TB, as shown in Table 3.

Subject 1	T4-TB [%]
MMDT-P [s]	3,2
SHAP IoF [%]	1,3
BBT [blocks]	14,3

Subject 2	T4-TB [%]
MMDT-P [s]	4,5
SHAP IoF [%]	19,7
BBT [blocks]	61,5

Subject 3	T4-TB [%]
MMDT-P [s]	-10,1
SHAP IoF [%]	1,4
BBT [blocks]	57,1

Subject 1	T4-TB [%]
QuickDASH [%]	42,8
OPUS-UEFS: usage [%]	5,0
OPUS-UEFS: goodness [%]	

Subject 2	T4-TB [%]
QuickDASH [%]	16,5
OPUS-UEFS: usage [%]	10,4
OPUS-UEFS: goodness [%]	

Subject 3	T4-TB [%]
QuickDASH [%]	1,3
OPUS-UEFS: usage [%]	0,0
OPUS-UEFS: goodness [%]	

Table 3: *Comparison between Hannes in T4 and the reference prosthesis in TB. Green cells for an improvement, red cells for a deterioration and yellow cells for equality.*

For what concerns the results of the exploratory study on the **"embodiment training"**, each subject was able to maintain on average the respiratory rate quite close to the targets. A bigger mean deviation was found for the NB condition and the standard deviations decreased over the trials. On average, each participant successfully accomplished the task more than half of the 16 trials in both conditions, with better results in the NB condition. The 12 healthy subjects gave on average higher scores in the SB condition and 2 differences resulted to be significant in favour of the SB condition in scales 3 and 4 (p=0,005 and p=0,004), related to the body-ownership sphere. The 2 amputees assigned higher scores with respect to the ones given by the healthy subjects. In the body-ownership scales (2, 3 and 4), amputee 1 expressed higher scores for the SB condition, whilst amputee 2 gave almost the same scores in both conditions.

The average time estimation for the 12 healthy subjects resulted lower than the real duration in both conditions and the lowest average estimation regarded the SB one. Also the amputees estimated lowers times, but the lowest estimation belongs to the NB condition. On average, considering the 12 healthy subjects, the proprioceptive drift was towards left in the SB condition and towards right in the NB condition. The 2 amputees instead presented drifts towards left in both conditions, but with a bigger mean deviation in the SB condition (Figure 10).

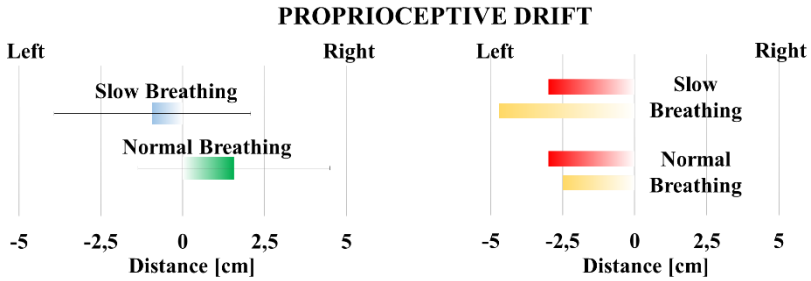


Figure 10: *Proprioceptive drift results. On the left the average results of the 12 healthy subjects, on the right the results of the 2 amputees (red for amputee 1, yellow for amputee 2).*

Discussion

Having regards to the results of the *evaluation*, it is possible to declare that the **embodiment**, the **user experience** and also the **functionality** were enhanced and *improved* with the domestic and constant usage over the three-month period. The subjects were able to exploit the prosthesis in several ADLs, taking always more advantage from the high efficacy in term of functionality. They became more confident with *Hannes* over time, increasing the control and hence achieving better performances. The improvements demonstrate this perceived feeling and therefore the good user experience and functionality accomplished. The objective methods regarding the embodiment demonstrated to be a valid tool of investigation, proving that a prolonged use can improve the integration of a prosthesis. Coherently, a good relationship between the user and the device can help in the enhancement of the embodiment of the device. Furthermore, the three subjects stated to prefer *Hannes* hand with respect to their commercial prostheses because of the natural behaviour that it provides, as confirmed by the improvements obtained with *Hannes* in T4 compared to the prostheses investigated at TB.

Considering the results of the *exploratory study* on the **"embodiment training"**, it can be said that the two conditions were on average feasible and that a learning effect occurred from about half of the session, as confirmed by the decreasing standard deviations. The 2 significant differences in favour of the SB condition in scales 3 and 4 (investigating the body-ownership, an aspect related to the embodiment process) demonstrate that this condition improved the embodiment of the virtual hand compared to the NB one. The lower time estimations and the drift towards left (towards the virtual hand) in the SB condition demonstrate that the subjects were more immersed in the spatially augmented reality and concentrated on the task in this condition. These conditions are supposed to facilitate the embodiment. Based on the scores assigned to the questionnaire, the time estimation and the proprioceptive drift, it can be said that the SB condition influenced more the embodiment of

the first amputee, whilst amputee 2 did not revealed a better “embodiment stimulation” condition.

Conclusion

In conclusion, the **pre-validation** verified the feasibility of the clinical protocol and the effects given by the prolonged used of the prosthesis *Hannes*. The time improved the user experience, the embodiment and the exploitation of the functionality related to *Hannes*. The designed methodology provides a valid evaluation. Hence, this preliminary study can be considered a useful strategy for the investigation and improvement of the embodiment of an upper limb prosthesis. Furthermore, considering the high appreciation of the subjects and the better results achieved, *Hannes* can be considered a good equivalent of the commercial prostheses, and maybe an even better solution. Having regards to the results, it can be said that *Hannes* was perceived by the subjects as part of their body rather than an external tool. The results of the exploratory study on the **“embodiment training”** verified the initial assumptions, confirming that the psychophysiological state induced by a slow breathing rate can facilitate and improve the embodiment process, in this case of a virtual hand. It can be concluded that the setup was robust in term of breaths detecting and the spatially augmented reality stimulating and immersive. Furthermore, the positive amputees’ feedback emphasized the potentiality of this custom-made tool as a valid at-home “embodiment training” for their prostheses.

Sommario

Introduzione e obiettivi

Le attività di ricerca sviluppate al Rehab Technologies IIT/INAIL Lab riguardano la traumatica perdita dell'effettore dell'arto superiore: la mano. La soluzione che permette di superare questa disabilità è la protesi. Il mondo protesico è in continuo sviluppo: dalle vecchie soluzioni che permettevano solamento la restaurazione dell'aspetto estetico, grazie all'innovazione tecnologica, oggigiorno le protesi possono assicurare il recupero sia delle funzionlità perse che dell'estetica. Le mani protesiche poliarticolate mioelettricamente controllate sono gli ultimi più avanzati dispositivi commercialmente disponibili in grado di offrire queste caratteristiche. Nonostante l'alto livello di tecnologia raggiunto, il tasso di abbandono delle protesi è ancora molto alto. La ragione di questo rifiuto può essere trovata nel basso livello di embodiment che caratterizza le protesi. L'embodiment definisce l'integrazione nello schema corporeo (e mentale) di un dispositivo esterno, in questo caso la protesi. Questa tesi si compone di due studi relativi a questo fenomeno.

Il primo studio ha investigato il livello di embodiment raggiunto con la nuova mano protesica *Hannes* (sviluppata da Rehab Lab) attraverso la pre-validazione di una sperimentazione clinica ufficiale post-market. Gli ***obiettivi primari*** erano il *miglioramento*, attraverso l'uso domestico, dell'**embodiment** e dell'**esperienza utente** (UX) di *Hannes* e la loro *valutazione* nel tempo. L'***obiettivo secondario*** riguardava la valutazione della **funzionalità**, aspetto che indirettamente influenza l'embodiment e che può comunque essere migliorato nello stesso modo attraverso l'utilizzo giornaliero. Inoltre, è stato condotto un *confronto* tra *Hannes* dopo l'uso prolungato e la protesi di uso comune.

Il secondo studio ha riguardato un'attività esplorativa focalizzata su uno strumento dedicato per **stimolare** e **"allenare"** l'**embodiment** di una rappresentazione virtuale della mano *Hannes*. L'ipotesi di base era che, con un'*induzione forzata* di uno *stato psicofisiologico* attraverso la modulazione del *respiro,* fosse possibile raggiungere una condizione fisica e mentale nella quale il **processo di embodiment** era *facilitato*. Precisamente, una *frequenza respiratoria lenta* avrebbe dovuto indurre meglio questo stato rispetto ad una normale. L'idea a lungo termine è quella di intrinsecamente indurre il processo di embodiment di una vera protesi attraverso l'allenamento virtuale con la mano virtuale, visto che queste due sono identiche.

Stato dell'arte

La struttura ossea e i muscoli che controllano la mano e il polso permettono a questi organi di eseguire numerosi e complicati movimenti, tra i quali la presa è il più rilevante. Infatti, la mano e il polso posseggono in totale 27 GDL[16]. La perdita di una mano può essere definita come un evento traumatico, specialmente per la riuscita delle ADLs. Una ricerca condotta dal *Ministero Italiano della Salute* dal 2006 al 2013 ha stimato, in Italia, circa 1600 nuove amputazioni di arto superiore ogni anno. Le protesi mioelettriche sono controllate dalla contrazione dei muscoli residui presenti nel moncone. La strategia di controllo più usata implementa una regolazione proporzionale grazie a due elettrodi superficiali (sEMG). Questi sEMG rilevano l'attività dei muscoli flessori ed estensori per rispettivamente chiudere e aprire la protesi. Le mani i-Limb, Bebionic e Michelangelo sono le principali protesi poliarticolate controllate mioelettricamente attualmente disponibili sul mercato, e *Hannes* è considerata equivalente a loro. Infatti, lo studio pre-market eseguito su *Hannes* ha confermato la sua usabilità e l'alta efficacia in termini di funzionalità rispetto agli altri dispositivi commerciali. La sperimentazione clinica post-market sulla quale la pre-validazione si basa è ispirata a questo studio clinico, ma l'attività principale è focalizzata sull'embodiment. Si è infatti dimostrato che l'embodiment favorisce il controllo della protesi e la sua accettazione.

Materiali

Hannes è una mano protesica poliarticolata controllata mioelettricamente che ha ricevuto il marchio CE nel 2017. È capace di restituire oltre il 90% della funzionalità persa e il suo processo di commercializzazione è in fase di sviluppo. *Hannes* è il risultato di un'attività di co-sviluppo tra ricercatori, pazienti, ortopedici e designer industriali, il quale ha permesso di renderla molto simile alla mano umana in termini di taglia, forma e comportamento cinematico (Figura 1).

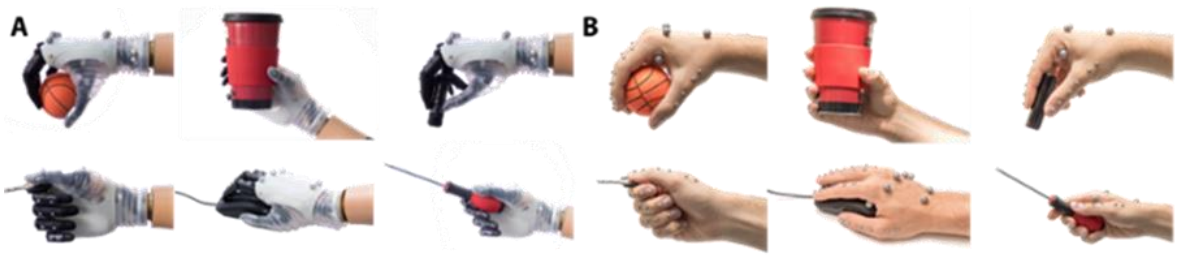


Figura 1: *La mano hannes* ***(A)*** *confrontata con la mano umana* ***(B)*** *durante attività di presa.*

[16] Gradi Di Libertà

La caratteristiche che rende *Hannes* unica è l'innovativo sistema DAG. La trasmissione meccanica integrata consiste di un meccanismo differenziale guidato da cavi capace di offrire al paziente una presa veloce e precisa. Questo meccanismo permette alla protesi di adattarsi alla forma di qualsiasi oggetto e di resistere a qualsiasi disturbo esterno, fornendo proprietà di presa simil-umane, come la robustezza, la stabilità e la coordinazione sinergica delle dita.

Metodi

La **pre-validazione** ha incluso tre utilizzatori di protesi mioelettrica. Questi ultimi erano infatti dotati rispettivamente della mano Bebionic, Variplus e Michelangelo. Lo studio è durato 3 mesi con regolari follow-up alla fine di ogni mese (T1 all'inizio, a seguire T2, T3, T4) per la valuazione dell'esperienza utente, dell'embodiment e della funzionalità di *Hannes* attraverso questionari e test. Inoltre, una valutazione è stata anche eseguita sulla mano di riferimento all'inizio dello studio (TB) per permettere un confronto. La valutazione ha sfruttato diversi metodi, riassunti in Figura 2.

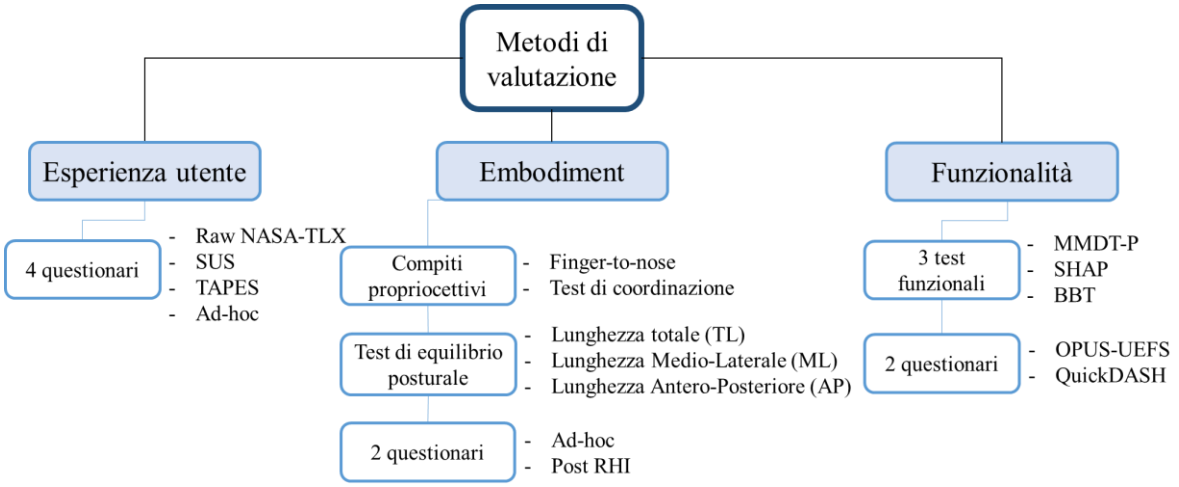


Figura 2: *Metodi di valutatione adottati nella pre-validazione.*

Alcuni di questi metodi sono internazionalmente validati: raw NASA-TLX, SUS, TAPES, OPUS-UEFS e QuickDASH come questionari mentre MMDT-P, SHAP e BBT come test funzionali. I compiti propriocettivi e il test di equilibrio posturale hanno introdotto metodi innovativi (Figura 3) per una valutazione obiettiva del livello di embodiment. Inoltre, due questionari sono stati specificatamente stilati per questo studio clinico per la valutazione dell'embodiment e dell'esperienza utente. Uno di questi veniva somministrato a seguito di una sessione di Rubber Hand Illusion (RHI) modificata, usata per rafforzare l'embodiment. In questa sessione, stimoli vibrotattili venivano dati al moncone simultaneamente al contatto visivo di un oggetto con la protesi.

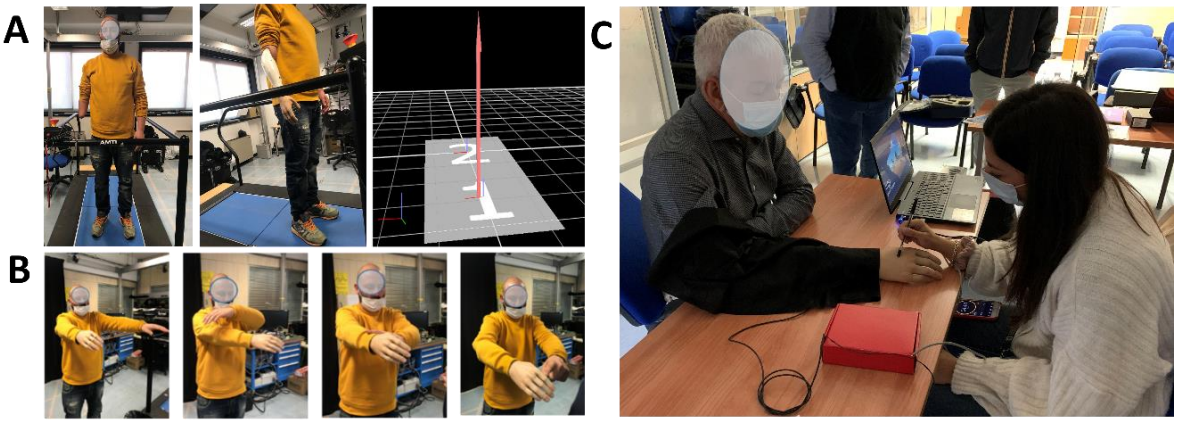


Figura 3: ***(A)*** *Test di equilibrio posturale,* ***(B)*** *Compiti propriocettivi e* ***(C)*** *RHI modificata.*

Lo studio esplorativo sullo strumento per l' **"embodiment training"** ha utilizzato una realtà virtuale dedicata spazialmente aumentata sviluppata nel software Unity e un set up molto basico per essere replicato a casa. 12 soggetti sani e 2 amputati sono stati inclusi in questo studio di fattibilità. Ai partecipanti è stato chieso di aumentare l'opacità di una mano virtuale (una copia virtuale 3D di *Hannes*) attraverso il corretto mantenimento di una frequenza respiratoria richiesta come target. Questo avrebbe permesso ad una sfera energetica (rappresentata mentre si muove verso la mano in Figura 4) di attivare una vibrazione visiva una volta sotto la mano. La vibrazione della mano appariva sullo schermo mentre simultaneamente una vibrazione tattile era applicata alla vera mano destra attraverso uno smartphone posizionato sotto la mano reale.

Figura 4: *Sequenza di scene durante l'esecuzione del trial.*

Il compito è stato somministrato (per 16 trial da un minuto ciascuno) con l'obiettivo di mantenere due frequenze respiratorie differenti:

1. Una frequenza respiratoria lenta (RL), circa 6 respiri/minuto
2. Una frequenza respiratoria normale (RN), circa 14 respiri/minuto

I respiri per l'elaborazione della frequenza respiratoria sono stati rilevati con un microfono posizionato di fronte alla bocca (Figura 5 **A**). La valutazione dell'embodiment per la mano virtuale è stato eseguito, alla fine dell'esperimento, con un questionario soggettivo e con la misurazione della deviazione propriocettiva (Figura 5 **B**).

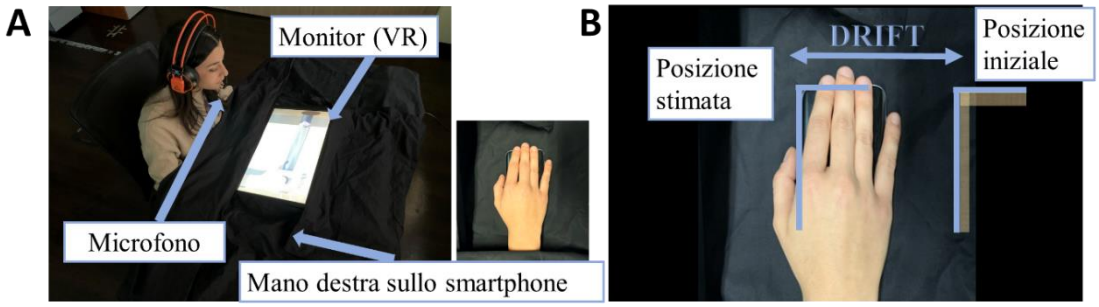


Figura 5: (A) *Set up e* ***(B)*** *deviazione propriocettiva.*

Risultati

L'**esperienza utente** ha mostrato un miglioramento nel tempo, come confermato dai trend in generale discendenti previsti nel punteggio del raw NASA-TLX e dai trend in generale ascendenti previsti nell'indice globale dei questionari SUS e TAPES (Figura 6).

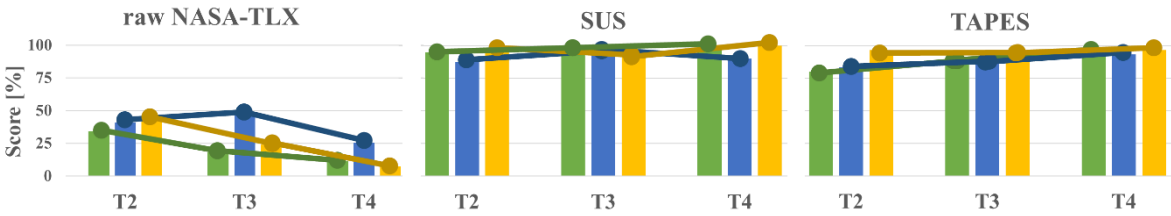


Figura 6: *Risultati dell'esperienza utente con Hannes per ogni tempo di investigazione (T2, T3, T4). Verde per soggetto 1, blu per soggetto 2 e giallo per soggetto 3.*

Anche il questionario Ad hoc, che non forniva un indice generale, ha mostrato punteggi migliorati nel tempo circa la UX. In generale, *Hannes* ha assicurato una UX migliore rispetto alle protesi di uso comune, così come evidenziato dai miglioramenti riportati in Tabella 1.

Subject 1	T4-TB [%]
Raw NASA-TLX [%]	54,8
SUS [%]	42,9
TAPES [%]	31,8

Subject 2	T4-TB [%]
Raw NASA-TLX [%]	16,2
SUS [%]	2,9
TAPES [%]	15,5

Subject 3	T4-TB [%]
Raw NASA-TLX [%]	83,0
SUS [%]	33,3
TAPES [%]	0,0

Tabella 1: *Confronto tra Hannes in T4 e la protesi di riferimento in TB. Celle verdi per un miglioramento, celle rosse per un peggioramento e celle gialle per un'uguaglianza.*

La valutazione dell'**embodiment** attraverso il questionario Ad hoc ha mostrato punteggi migliorati nel tempo per ogni soggetto negli item relativi a questo aspetto. Il questionario circa la sessione di RHI modificata, così come il questionario Ad hoc, non forniva un indice complessivo ed è stato valutato item per item. I soggetti 1 e 3 hanno leggermente migliorato i loro punteggi, mentre il soggetto 2 ha mostrato un lieve peggioramento nei punteggi. I compiti propriocettivi hanno mostrato un trend generale verso la deviazione 0, che era il target ideale. I test propriocettivi hanno quindi mostrato un miglioramento nel tempo e, inoltre, risultati migliori con *Hannes* rispetto alla valutazione basale con le mani di riferimento. La lunghezza dei percorsi totali TL, medio-laterali ML e antero-posteriori AP

indagati nelle due condizioni (occhi aperti e occhi chiusi) con il test di equilibrio posturale hanno mostrato, come ci si aspettava, dei trend discendenti nel tempo (Figura 7).

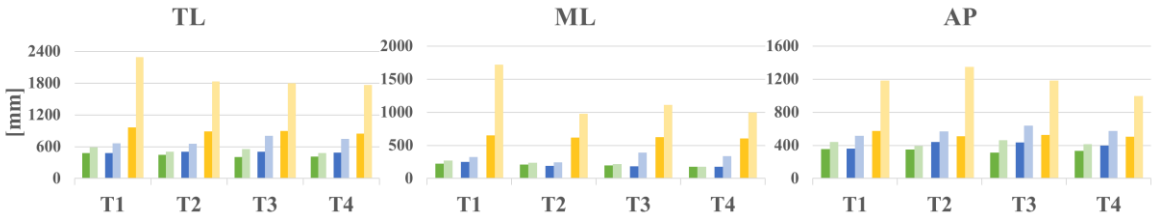


Figura 7: *Risultati del test di equilibrio posturale con Hannes per ogni tempo di acquisizione (T1, T2, T3, T4). Colori scuri per le condizione occhi-aperti, colori chiari per la condizione la condizione occhi-chiusi. Verde per soggetto 1, blu per soggetto 2 e giallo per soggetto 3.*

Il confronto tra le oscillazioni con *Hannes* e con le protesi commerciali ha mostrato risultati migliori (oscillazioni minori) con *Hannes*, ma il confronto tra *Hannes* e l'assenza di qualsiasi protesi ha presentato numerosi peggioramenti (Tabella 2).

Subject 1	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	15,0	-16,9
	EC	24,0	14,3
ML [mm]	EO	22,6	-8,9
	EC	37,9	28,8
AP [mm]	EO	11,3	-19,4
	EC	17,4	8,1

Subject 2	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	6,9	-30,6
	EC	14,7	-3,9
ML [mm]	EO	27,4	-11,9
	EC	18,7	-4,1
AP [mm]	EO	3,9	-29,1
	EC	16,9	1,6

Subject 3	Condition	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	22,7	20,0
	EC	13,1	1,5
ML [mm]	EO	31,2	30,8
	EC	36,4	29,4
AP [mm]	EO	-2,7	-14,6
	EC	-0,9	-16,1

Tabella 2: *Confronto tra Hannes in T4 e la protesi di riferimento in TB e l'assenza di protesi. Celle verdi per un miglioramento, celle rosse per un peggioramento e celle gialle per un'uguaglianza.*

La **funzionalità** è migliorata nel tempo. Questo è apprezzabile con il trend discendente nel test MMDT-P e i trend ascendenti sia nell'IoF dello SHAP che nel test BBT (Figura 8).

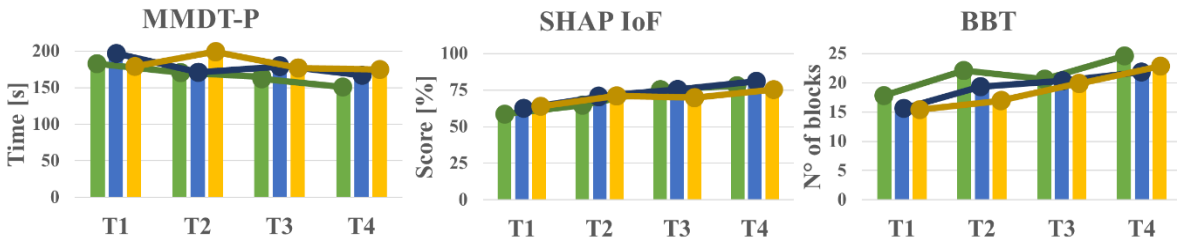


Figura 8: *Risultati dei test funzionali con Hannes per ogni tempo di investigazione (T2, T3, T4). Verde per soggetto 1, blu per soggetto 2 e giallo per soggetto 3.*

L'efficacia migliorata nelle ADLs è dimostrata nel tempo dal trend in generale discendente del punteggio totale del QuickDASH (eccetto per il soggetto 1) e dal trend in generale ascendente della percentuale di utilizzo calcolata con l'OPUS-UEFS (eccetto per il soggetto 3) (Figura 9).

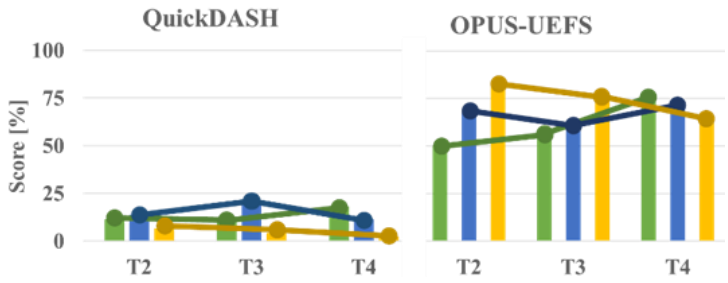


Figura 9: *Risultati dei questionari funzionali con Hannes per ogni tempo di investigazione (T2, T3, T4). Verde per soggetto 1, blu per soggetto 2 e giallo per soggetto 3.*

In generale, al termine dello studio (T4) *Hannes* ha migliorato la funzionalità rispetto alle protesi di riferimento valutate in TB, così come mostrato in Tabella 3.

Subject 1	T4-TB [%]
MMDT-P [s]	3,2
SHAP IoF [%]	1,3
BBT [blocks]	14,3

Subject 2	T4-TB [%]
MMDT-P [s]	4,5
SHAP IoF [%]	19,7
BBT [blocks]	61,5

Subject 3	T4-TB [%]
MMDT-P [s]	-10,1
SHAP IoF [%]	1,4
BBT [blocks]	57,1

Subject 1	T4-TB [%]
QuickDASH [%]	42,8
OPUS-UEFS: usage [%]	5,0
OPUS-UEFS: goodness [%]	

Subject 2	T4-TB [%]
QuickDASH [%]	16,5
OPUS-UEFS: usage [%]	10,4
OPUS-UEFS: goodness [%]	

Subject 3	T4-TB [%]
QuickDASH [%]	1,3
OPUS-UEFS: usage [%]	0,0
OPUS-UEFS: goodness [%]	

Tabella 3: *Confronto tra Hannes in T4 e la protesi di riferimento in TB. Celle verdi per un miglioramento, celle rosse per un peggioramento e celle gialle per un'uguaglianza.*

Per quanto riguarda i risultati dello studio esplorativo sull' **"embodiment training"**, ogni soggetto è stato in grado di mantenere in media la frequenza respiratoria abbastanza vicino ai target. Una deviazione media più grande è stata trovata nella condizione con RN e le deviazioni standard sono diminuite con l'avanzare dei trial. In media, ogni partecipante ha terminato con successo il compito più della metà dei 16 trial in entrambe le condizioni, con risultati migliori nella condizione con RN. I 12 soggetti sani hanno dato in media punteggi più alti nella condizione con RL e 2 differenze sono risultate significative a favore della condizione con RL nelle scale 3 e 4 (p=0,005 e p=0,004), relative alla sfera dell'appartenenza corporea. I due amputati hanno assegnato punteggi più alti rispetto a quelli dati dai soggetti sani. Nelle scale di appartenenza corporea (2, 3 e 4), l'amputato 1 ha espresso punteggi più alti nella condizione con RL, mentre l'amputato 2 ha dato più o meno gli stessi risultati in entrambe le condizioni. La media delle stime del tempo per i 12 soggetti sani è risultata essere minore della reale durata in entrambe le condizioni, e la stima media più bassa riguardava quella con RL. Anche gli amputati hanno stimato tempi minori, ma la stima più bassa appartiene alla condizione con RN. In media, considerando i 12 soggetti sani, la deviazione propriocettiva è risultata verso sinistra nella condizione con RL, e verso destra nella condizione con RN. I due amputati invece hanno presentato deviazioni verso sinistra

in entrambe le condizioni, ma con una deviazione media maggiore nella condizione con RL (Figura 10).

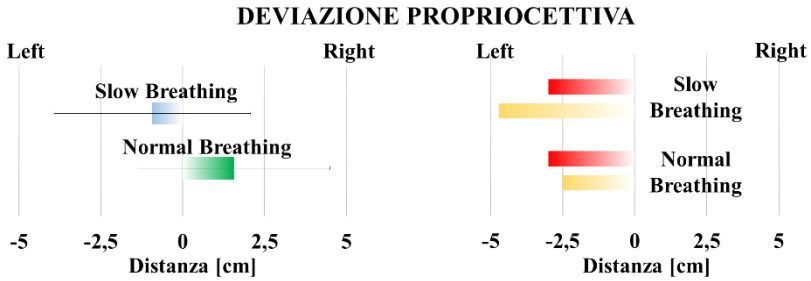


Figura 10: *Risultati delle variazioni propriocettive. A sinistra, i risultati medi dei 12 soggetti sani, a destra i risultati dei due amputati (rosso per amputato 1, giallo per amputato 2).*

Discussione

Considerando i risultati della *valutazione* è possibile dichiarare che l'**embodiment**, la **user experience** e anche la **funzionalità** sono state rafforzate e sono *migliorate* con l'uso costante e domestico nei tre mesi. I soggetti sono stati in grado di sfruttare la protesi in numerose ADLs, avvantaggiandosi sempre più della grande efficacia in termine di funzionalità. Sono diventati sempre più confidenti con *Hannes* col passare del tempo, aumentando il controllo e quindi raggiungendo delle esecuzioni migliori. I miglioramenti dimostrano questa sensazione e pertanto la buona UX e funzionalità ottenute. I metodi oggettivi riguardanti l'embodiment hanno dimostrato essere uno strumento valido per l'indagine, provando che un uso prolungato può migliorare l'integrazione di una protesi. Coerentemente, una buona relazione tra l'utente e il dispositivo può aiutare nel rafforzamento dell'embodiment del dispositivo. Inoltre, i tre soggetti hanno dichiarato di preferire la mano *Hannes* rispetto alle loro protesi commerciali per via del comportamento naturale che offre, così come confermato dai miglioramenti ottenuti con *Hannes* in T4 in confronto alle protesi studiate in TB.

Considerando i risultati dello *studio esplorativo* sull' **"embodiment training"**, si può dire che le due condizioni sono state in media raggiungibili e che un effetto di apprendimento si è manifestato da circa metà della sessione, così come confermato dal diminuire delle deviazioni standard. Le due differenze significative a favore della condizione con RL nelle scale 3 e 4 (che indagavano l'appartenenza corporea, un aspetto legato al processo di embodiment) dimostrano che questa condizione ha migliorato l'embodiment della mano virtuale rispetto a quella con RN. Le più basse stime temporali e le deviazioni verso sinistra (verso la mano virtuale) nella condizione con RL dimostrano che i soggetti erano più immersi nella realtà spazialmente aumentata e più concentrati sul compito in questa

condizione. Si suppone che queste condizioni facilitino l'embodiment. In base ai punteggi assegnati al questionario, la stima temporale e la deviazione propriocettiva, si può dire che la condizione con RL ha influenzato di più l'embodiment del primo amputato, mentre l'amputato 2 non ha rivelato una condizione in grado di stimolare meglio l'embodiment.

Conclusioni

In conclusione, la **pre-validazione** ha verificato la fattibilità del protocollo clinico e gli effetti dati dall'uso prolungato della protesi *Hannes*. Il tempo ha migliorato l'esperienza utente, l'embodiment e lo sfruttamento della funzionalità relativa ad *Hannes*. La metodologia concepita fornisce una valida valutazione. Questo studio preliminare può essere quindi considerato una strategia utile per l'investigazione e il miglioramento dell'embodiment di una protesi di arto superiore. Inoltre, considerando il grande apprezzamento dei soggetti e i miglior risultati ottenuti, *Hannes* può essere considerata un buon equivalente delle protesi commerciali, e forse anche una soluzione migliore. In base ai risultati ottenuti, si può dire che *Hannes* è stata percepita dai soggetti come parte del loro corpo più che uno strumento esterno.

I risultati dello studio esplorativo sull' **"embodiment training"** hanno verificato le ipotesi iniziali, confermando che lo stato psicofisiologico indotto da una frequenza respiratoria lenta può facilitare e migliorare il processo di embodiment, in questo caso di una mano virtuale. Si può concludere che il setup è stato affidabile nella rilevazione dei respiri e che la realtà dedicata spazialmente aumentata è stata stimolante e immersiva. Inoltre, i feedback positivi degli amputati hanno enfatizzato la potenzialità di questo strumento dedicato come valido "embodiment training" casalingo per le loro protesi.

Introduction

The hand is one of the most complex and interesting example of engineering, designed in the human body by the nature. The human hand allows a powerful grip but, at the same time, it can also guarantee the manipulation of tiny objects with great precision. This versatility sets us apart from every other creature on the planet. The loss of this organ brings a severe disability and impedes the normal performance of all daily activities, as well as it modifies the aesthetic aspect of the amputee. Furthermore, this event causes psychological and psychosocial impairments. In the most extreme cases, the loss can interest both arms, making it evident how this event can impact someone's life. The development of the first prosthesis dates back to the Egyptian Age. A prosthesis is, for definition, an artificial device able to replace a missing or impaired part of the body. First, the aim of the prosthesis was mostly the restoration of the aesthetic aspect, but over the time, especially after the Second World War, which caused a very high number of amputees, engineers focused on the study of the so called "intelligent" prosthetics. These novel prostheses aspire to compensate the missing limb both from an aesthetic and functional point of view. The hand prostheses, in particular, exhibit a shape very similar to the human one and are able to detect the intention of the amputee, permitting the execution of some movements. Nowadays, the market offers some interesting solutions capable to restore a good percentage of the missing functionalities. Nevertheless, the abandonment rate is still high. This seems to be caused by the poor ownership perception of the user about his prosthesis, which is seen as an external tool rather than a real body part substitution. The appropriate term which defines the integration of external devices into the corporal scheme is *Embodiment*. The embodiment is nowadays of great interest since it influences the prosthesis' usage. This is why it is object of novel studies which try to evaluate and stimulate it.

Two studies have been carried out during the realization of this thesis that were aimed at achieving the above objectives. They refer to the evaluation and to the improvement, respectively, of the embodiment of an innovative upper-limb prosthesis, the Hannes system. Both studies were developed at the Istituto Italiano di Tecnologia (IIT), GE, precisely in the Rehab Technologies Lab, a joint lab between IIT and INAIL.

The two different exploratory studies are:

1. The **pre-validation** of the post-market clinical trial with *Hannes.*

   This research has been conducted on three patients with the poly-articulated myoelectric prosthetic hand *Hannes* and for a three-month period, with regular follows up each month. Besides the evaluation of the embodiment and its improvement through the domestic use, also the user experience (in term of appreciation level and usability) and the functionality (in term of practical efficacy) were evaluated and improved with the daily usage. Both these aspects influence and have consequences on the embodiment. Subjective methods such as validated questionnaires and objective measures were used. Another further aspect under observation was the comparability of the innovative prosthesis *Hannes* with respect to the well-known commercial hand prostheses.

2. The exploratory study on the **embodiment stimulation**.

   The problems related to the embodiment of a prosthesis could be surpassed if this untouchable phenomena could be stimulated and trained in a targeted way. The exploratory study on the embodiment aimed to accomplish this goal. A custom-made spatially augmented reality was designed and it was investigated if a forced psychophysiological state through the breathing rate was able to induce a physical and mental condition in which the embodiment was facilitated. The device to be embodied was a virtual representation of the *Hannes* hand. The evaluation methods had different nature. Both a subjective questionnaire and on objective measurement (of the proprioceptive drift) were used. The feasibility of the experiment and the assessment of the assumptions were the main goals. In fact, the preliminary study was conducted on 12 healthy subjects and only on 2 amputees.

1 State of the art

In this Chapter, several aspects regarding the hand and what its loss concerns will be described. In order to contextualize the study, a short introduction about the anatomy, physiology and kinematics of the hand is provided. The impact of upper limb amputations is hence discussed, together with the state of the art of upper limb prostheses. The most relevant and commercially available prostheses are thus described. Following, the novel myoelectrically controlled, poly-articulated, prosthetic hand called *Hannes,* is firstly presented and then compared with the reference prostheses during a pre-market clinical validation. Finally, the embodiment topic is addressed, with the novel methods to evaluate and stimulate it.

1.1 The wrist and the hand

The upper limb can be described as a system in which the main effector organ is the hand.
The human hand is an articulated apparatus used to identify and manipulate objects, as a form of communication through manual gestures and to assist physical executions, such as lifting heavy objects, climbing, riding a bicycle, etc. The capability to exert a precise amount of pressure to properly perform grasping tasks makes the hand essential for most of daily life activities.
It also embeds a very precise sensory feedback which is used to obtain multiple information about objects or surfaces in contact such as shape, size, texture, weight, orientation and thermal properties.

1.1.1 Anatomy

As shown in Figure 11 the wrist consists of 8 carpal bones. The carpal bones are arranged in two rows. Three bones of the proximal row (scaphoid, lunate and triquetrum) articulate in the forearm with the radius realising the radiocarpal joint. The proximal row articulates with the distal row forming the midcarpal joint. The proximal carpal row bones can be described as an intercalated segment because no tendons insert upon them and their motion is entirely dependent on mechanical forces from the surrounding articulations. The proximal carpal bones lunate and triquetrum also articulate with the distal ulna forming the ulnocarpal joint. The distal row carpal bones are tightly bound to one another through intercarpal ligaments, hence the motion between them can be considered negligible. They articulate with the thumb and the fingers through the carpometacarpal joints.

It is important to introduce the forearm because it plays a fundamental role for the control and support of the hand and especially of the wrist. The forearm, which plays a fundamental role for controlling and supporting the hand and the wrist, is the portion of the upper limb which extends from the elbow to the wrist and contains two main bones: the radius and the ulna. These latter articulate with each other at the proximal and distal radioulnar joints. In the proximal side, the head of the radius articulates with the radial notch of the ulna and with the distal humerus to form the elbow joint. In the distal side, the ulnar notch of the radius articulates with the ulnar head and with three of the four proximal carpal bones of the wrist realising the radiocarpal trochoid joint, whilst the ulna articulates with two proximal carpal bones forming the ulnocarpal joint, as already cited above.

The hand has a dorsal and palmar surfaces and it is composed by 5 metacarpal bones in the palm and 14 phalangeal bones that make up the digits (Figure 11). The 5 metacarpal bones are quite long with respect to the other hands' bones. They articulate with the adjacent carpal bones in the distal row, creating the carpometacarpal joints [1]. The head of these bones are smooth and rounded to fit into a concavity at the base of the proximal phalanx at the metacarpophalangeal joints. Each finger has three bones: the proximal, the middle and the distal phalanx, except for the thumb, which has only the proximal and the distal phalanx. In the fingers, the proximal phalanges distally articulate with the middle phalanges forming the proximal interphalangeal joints. These latter middle phalanges finally articulate with the distal phalanges through the distal interphalangeal joints. In order from the thumb the digits are called index, middle, ring and little finger.

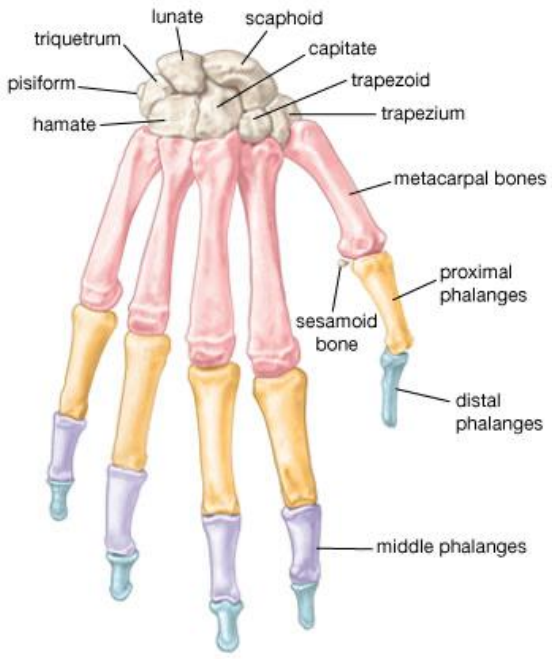


***Figure 11**: Bones of the hand and wrist.*

There are over 30 muscles which control the hand and the wrist, working together in a highly complex way. Most of these movements are permitted by forearm muscles, known as the extrinsic hand muscles (Figure 12).

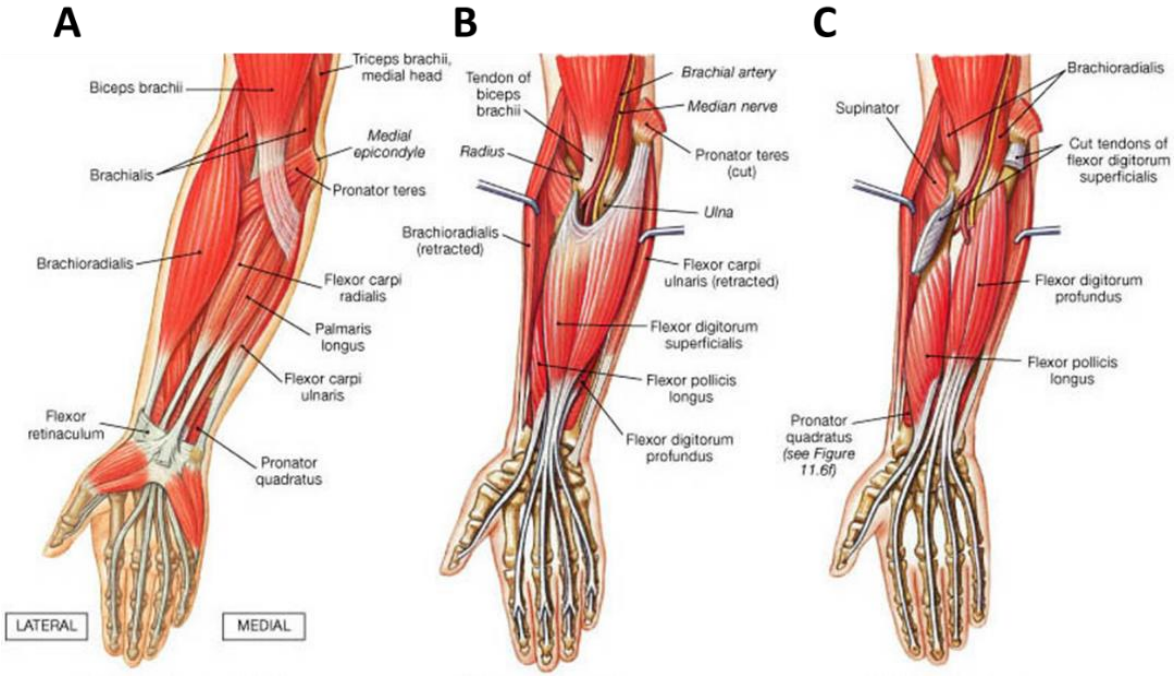


***Figure 12**: Extrinsic hand muscles **A)** Ventral view, superficial, **B)** Ventral view, middle and **C)** Ventral view, deep.*

The small muscles located within the hand are instead called intrinsic muscles (Figure 13). They provide fine motor movements.

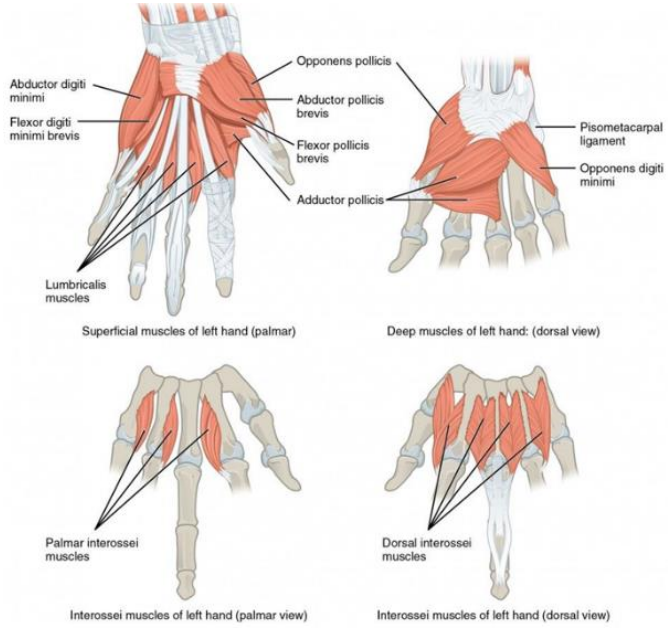


***Figure 13:** Intrinsic hand muscles.*

Hand muscles

The intrinsic muscles which control the hands fine movements are:

- Four dorsal and three palmar interossei muscles. The dorsal interossei allow the spread of the fingers away from each other. The palmar interossei pull the fingers together.
- Three hypothenar muscles: the abductor digiti minimi, which allows the small finger to pull away from the ring finger, the flexor digiti minimi, which allows the small finger to bend at the metacarpophalangeal joint, and the opponens digiti minimi, which permits the small finger to move towards the thumb.
- Lumbrical muscles. These muscles allow the fingers to straighten.

The extrinsic muscles located in the forearm but still controlling the hand's movements are:

- The Flexor Digitorum Profundus.
- The Flexor Digitorum Superficialis.
- The Extensor Indicis Proprius, which permits the independent straighten of the index finger.
- The Extensor Digitorum Communis.
- The Extensor Digiti Minimi.

Thumb muscles

The thumb is moved by 4 intrinsic muscles:

- The Adductor Pollicis, which provide power for pinching.
- The Thenar Flexor Pollicis Brevis, which straighten the thumb at its middle joint and bend the thumb toward the small finger.
- The Thenar Abductor Pollicis Brevis, which pulls the thumb away from the index finger.
- The Thenar Opponens Pollicis, which brings the thumb away from the fingers allowing the grasping of objects and the opposition movements.

The 3 extrinsic muscles which control the thumb and reside in the forearm are:

- The Abductor Pollicis Longus.
- The Flexor Pollicis Longus, which allows the bending of the thumb's tip.
- The Extensor Pollicis Longus, which straighten the thumb's tip.

Wrist muscles

The muscles responsible for the wrist movements are distinguished in 4 groups in relation with the two wrist DOFs: the flexion/extension and the abduction/adduction [2].

1. The anterior cubital group for the flexion and the adduction.
2. The posterior cubital group for the extension and adduction.
3. The palmar group for the flexion and abduction
4. The radial group for the extension and abduction.

The pronation and supination of the wrist is actuated through the muscular activity of four paired muscles:

- A short and flat muscle, which works by rotation.
- A long muscle, inserted in one of the two curves' apex of the radius.

The muscles which control the supination are:

1. The short supinator twisted around the radius' neck and acting by rotation.
2. The biceps, inserted in the curve's apex of the supination and acting for traction.

The muscles which control the pronation are:

1. The pronator quadratus, wrapped around the inferior extremity of the ulna and acting by rewrapping the ulna in relation to the radius.
2. The pronator teres, inserted in the curve's apex of the pronation and acting for traction.

The ligaments have the function to assure joint stability and they can be divided into extrinsic and intrinsic based on their location. The muscles and the skin of the whole hands are innervated by the ulnar, radial and median nerves, which ramify extensively in the surrounding space.

1.1.2 Kinematics

In total the human hand (including the wrist) has 27 degrees of freedom, therefore showing a high complexity, a wide range of motion and innumerable movements. Hereafter the main degrees of freedoms are reported.

The wrist with its mobility and stability is essential for good hand function. Individually considered the radiocarpal joint of the wrist has 2 degrees of freedom, allowing 2 different pairs of movements. Considering the hand in the anatomical position, that is a complete supination, the wrist movements are:

A. **Flexion/Extension** movements in the sagittal plane (horizontally outlined in Figure 14 **A**) around a transversal axis (shown in Figure 14 **A** as AA') included in the frontal plane (vertically outlined in Figure 14 **A**). During the flexion the palmar side of the hand approaches the ventral side of the forearm, whilst in extension the dorsal face approaches the dorsal part of the forearm (Figure 14 **B**).
B. **Radial/Ulnar deviations**, also called **abduction/adduction**, in the frontal plane (vertically outlined in Figure 14 **A**) around an anterior-posterior axis (shown in Figure 14 **A** as BB') included in a sagittal plane (horizontally outlined in Figure 14 **A**). During the radial deviation/abduction the hand approaches the radial side of the forearm (towards the thumb), while during the ulnar deviation/adduction it approaches the ulnar side (Figure 14 **C**).

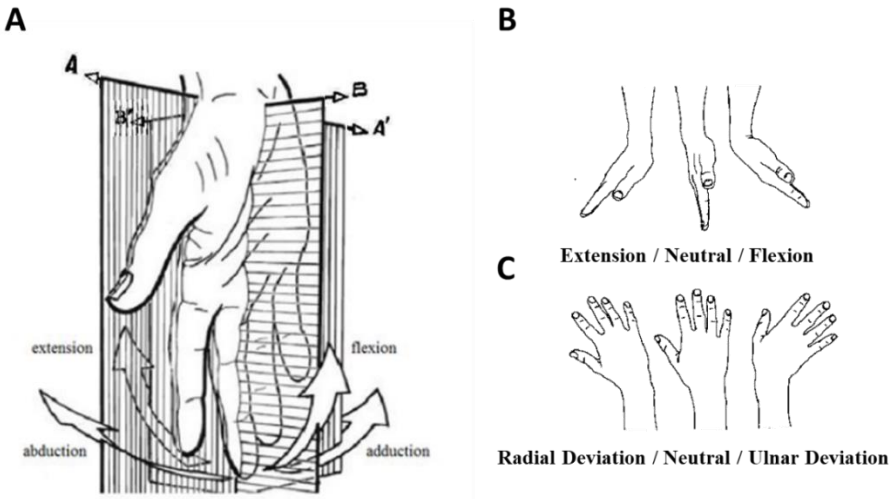


Figure 14: The two degrees of freedom of the wrist, **B)** Flexion/Extension and **C)** Radial/Ulnar deviation.

The pronation and supination of the wrist is permitted thanks to the rotational movement of the forearm along its longitudinal axis, with the intervention of two joints: the proximal radio-ulnar joint and the distal radio-ulnar joint. This third added DOF is essential for the control of the hand, allowing the hand to grasp or hold an object in any angle. When the elbow is flexed at 90° and it is in contact with the body the pronation and supination (Figure 15) of the wrist and hand can be studied:

A. The **supination** is obtained when the hand is perfectly in the horizontal plane, the hand's palm is directed upwards and the wrist is outwards. The radius and ulna are placed face-to-face, the ulna medially and the radius laterally. The respective longitudinal axes are parallel. The flexor muscles of the forearm move in front of radius and ulna during supination.
B. The **neutral position** is obtained when the hand is in the vertical plane, parallel to the sagittal plane of the body's symmetry. The wrist's direction is upwards and the palm is inward.
C. The **pronation** is actuated when the hand is in the horizontal plane (not perfectly because of the curve of the radius in the sagittal plane), the palm is turned downwards and the wrist is inward. In this configuration radius and ulna intersect. The radius is proximally lateral and distally medial to the ulna, passing in front of this latter. The flexor muscles interpose themselves between radius and ulna during pronation.

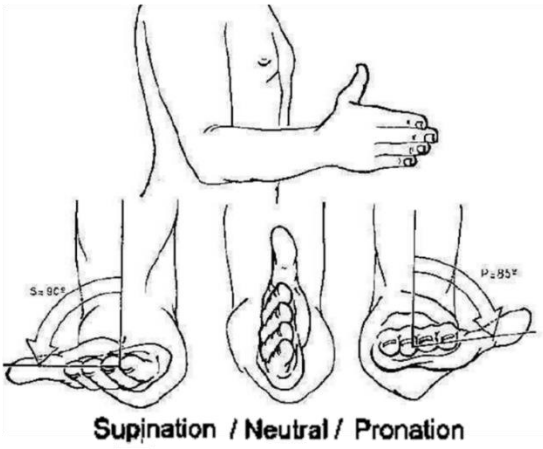


Figure 15: *Pronation and Supination of the wrist.*

The hand is the operating extremity of the upper limb. The 4 metacarpophalangeal condyloid joints of the fingers are capable of:

A. **Flexion** (fingers towards the hand's palmar surface) and **extension** (fingers toward the hand's dorsal surface) around a transversal axis passing through the metacarpophalangeal joints (Figure 16 **A**).
B. **Abduction/adduction** movements (Figure 16 **B**). During the abduction the fingers moves away from the midline of the hand, while in the adduction they move towards it.

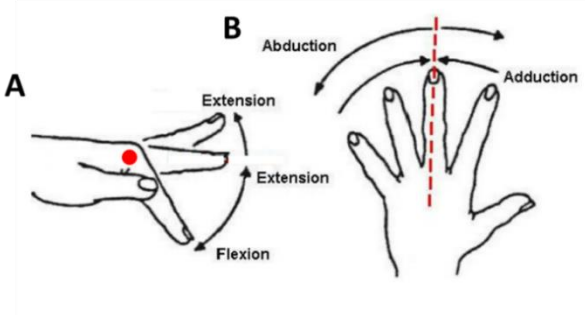


Figure 16: A) *Flexion and Extension and* ***B)*** *Abduction and Adduction of the of the metacarpophalangeal joints of the fingers.*

The eight interphalangeal joints in the fingers are only capable of **flexion** and minimal **extension** around the transversal axes passing through the phalangeal joints (Figure 17).

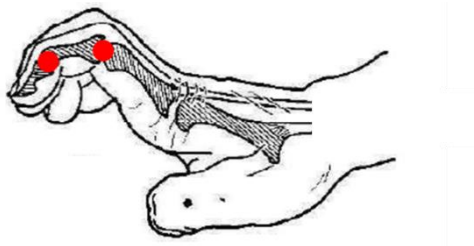


Figure 17: *Flexion and Extension of the interphalangeal joints of the fingers.*

The thumb is fundamental for the implementation of the grasps. This important role comes from the position in which the thumb is set with respect to the other fingers: it is able to perform opposition movements joining the fingers (individually or globally) to realise the grasp or to move away from them through contro-opposition movements to release the grasp. The several opposition movements' possibilities allow a huge variety of grasps and actions (Figure 18). These movements are the result of the combination of different degrees of freedom belonging to the thumb's joints.

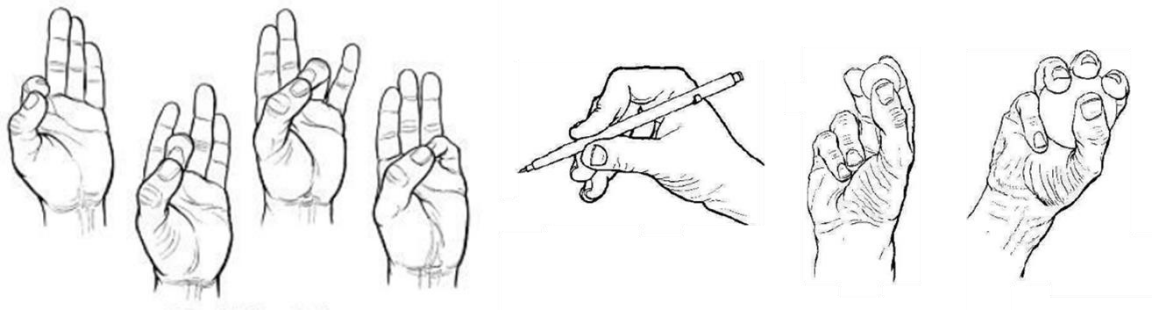


Figure 18: *Different hand gestures allowed by the thumb.*

The carpometacarpal joint of the thumb can produce:

- **Abduction**, the separation of the first metacarpal with respect to the second one in plane F, and **adduction**, the inverse approaching movement (along narrow 1 of Figure 19).
- **Flexion**, the progressive movement which bring the first metacarpal forward, and **extension**, the inverse returning movement (along narrow 2 of Figure 19).

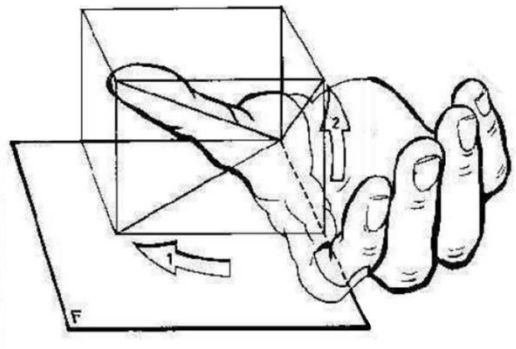


Figure 19: *The two DOFs of the carpometacarpal joint of the thumb.*

The metacarpal joint of the thumb in the erect position has 2 DOFs:

- The **pure flexion** (arrow 1 of Figure 20) around the transversal axis f_1 of Figure 20).
- The complex movements of the longitudinal flexion-inclination-rotation:
    - **Flexion-ulnar inclination-supination** (arrow 2 of Figure 20) around the oblique axis f_2 of Figure 20.
    - **Flexion-radial inclination-pronation** (arrow 3 of Figure 20) around the other oblique axis f_3 of Figure 20.

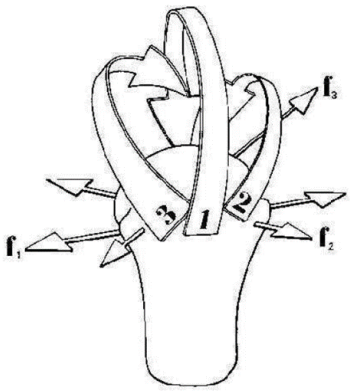


Figure 20: *Posterior view of the metacarpal head.*

The interphalangeal joint of the thumb, like the interphalangeal joints of the fingers, is only able to perform around the transversal axis passing through the center of curvature of condyles of the head of the first phalanx:

A. **Flexion** (Figure 21 **A**)
B. Minimal **extension** (Figure 21 **B**)

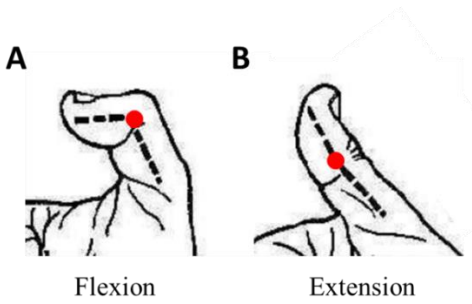


Figure 21: A) *Flexion and* ***B)*** *Extension of the interphalangeal joint of the thumb.*

It must be added that the wrist and the carpometacarpal joints are able to perform the movement of the circumduction using the sequential combination of flexion, adduction, extension, and abduction movements.

1.2 Upper limb amputations

The loss of a limb always results in some physical and psychological effects. It can have a direct impact on dexterity and even mobility, affecting a person's ability to walk or balance correctly. The biomechanics of the body changes, trying to compensate the missing limb. This result in the excessive use of the rest of the body or incorrect body postures, producing an extreme fatigue [3]. In addition, people commonly experience phantom-limb pain [4]. Losing a limb has been found to dramatically change a person's sense of body-image and, consequently, self-image, impacting on a person's satisfaction with life, social life and nature of social interactions.

1.2.1 Epidemiology and etiology

Epidemiology is the study of the distribution (who, when, and where), patterns and determinants of health and disease conditions in defined populations. From an epidemiologic outlook, an exhaustive analysis of the amputations occurred in the world is not possible, since several countries do not have files related to them. To have an idea of the impact of this condition, from a statistical analysis of the *Italian Ministry of Health,* conducted from 2006 to 2013, in Italy, there were estimated 1600 new upper limb amputations every year.

Generally, etiologically speaking, the main causes which bring to amputation are three: diseases, traumas and congenital malformations. The data revised in 2014, at the beginning of the development of *Hannes* project, supplied by the *Italian Ministry of Health* and the *National Institute of Health* , reports that the 70% of the amputations are caused by vascular and infective pathologies (mainly people of the age range 61-70 years), the 22% by traumatic events such as car accidents, workplace or home accidents (mainly people of the age range 1-30 years), the 5% by tumors (mainly people of the age range 11-20 years), and the 3% by congenital malformations (see Table 4).

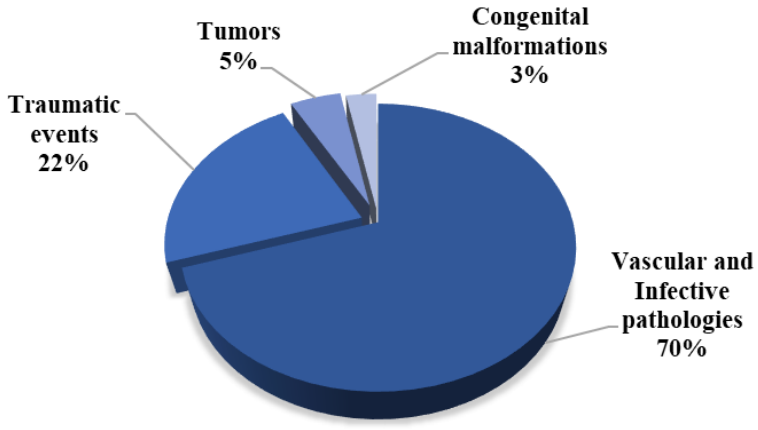


***Table 4**: Percentage of amputation's causes.*

The prevalence of these causes varies from region to region and has changed over the years. The development of the surgical techniques, the medical treatments and the fast operating times have reduced the operations of amputation following traumatic events, while, on the other hand, the number of people affected by diseases that can lead to the necessity of an amputation has increased. This fact is determined by the increase of human lifetime, with the major incidence of chronic-degenerative pathologies of the cardio-vascular apparatus typical of old people, and by the millennials' lifestyle, with bad life and food habits [5].
Only a small part of amputations derives from tumours, where the affected limbs are ablated to prevent the illness's development. Congenital deficiencies affect new-borns in different ways. They can have malformed, shorter or totally absent limbs. Depending on the nature and the extension of the malformation, the limbs can be surgically removed and, together with the short limbs, be substituted by the prosthesis.

The amputations caused by vascular and infective diseases mostly concern the lower limbs, whereas most upper limb amputations are traumatic in origin [6].

Despite the descending trend over the years, the number of amputations in the whole world is still high. It is enough to think about the amputations occurring in Italy, as showed by studies and data supplied by the *Ministry of Health* and the *National Institute of Health*. Every year, there are around from 8000 to 11000 new amputations, of these 3600-4000 regard the upper limb. This justifies the continuous research and development in the prosthetic field, with the aim to improve the technology and therefore amputees' quality of life.

1.2.2 Classification of upper limb amputations

The levels of upper limb loss can be classified, according to Figure 22, as transcarpal, wrist disarticulation, transradial, elbow disarticulation, transhumeral, shoulder disarticulation and forequarter [7].

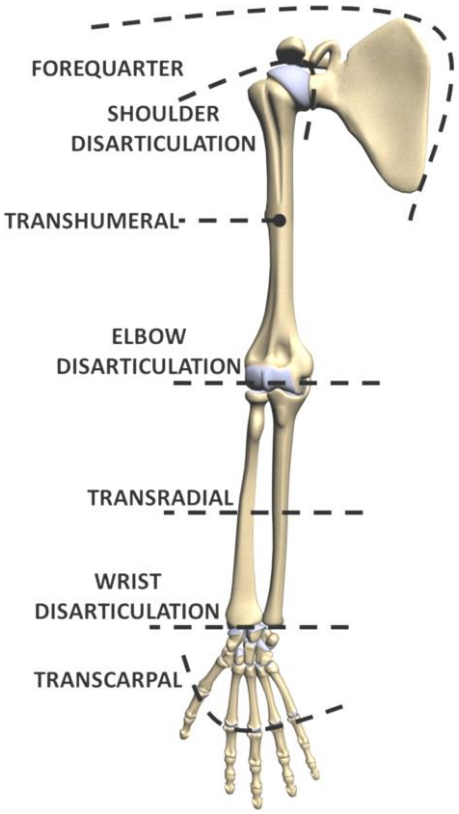


***Figure 22**: Different level of upper limb amputations.*

Regarding upper limb amputations, the most common are the amputation and disarticulations of the fingers. Italian statistics and data provided by the *Ministry of Health* and a report by *Institute of Management Studies* (*ISTUD)* show that this level of amputation occupies the 84,2% of the total Italian upper limb amputations in the period from 2006 and 2013.

The other incidences of amputation are distributed as follows and shown in Table 5:

- Amputation (not defined level) of the upper limb: 1,04%.
- Amputation and disarticulation of the thumb: 9%.
- Amputation at the level of the hand: 1,96%.
- Disarticulation of the wrist: 0,63%.
- Amputation of the forearm: 1,04%.
- Disarticulation of the elbow: 0,11%.
- Amputation at the humerus level: 1.16%.
- Disarticulation of the shoulder: 0,4%.
- Thoracic interscapulum amputation: 0,45%.

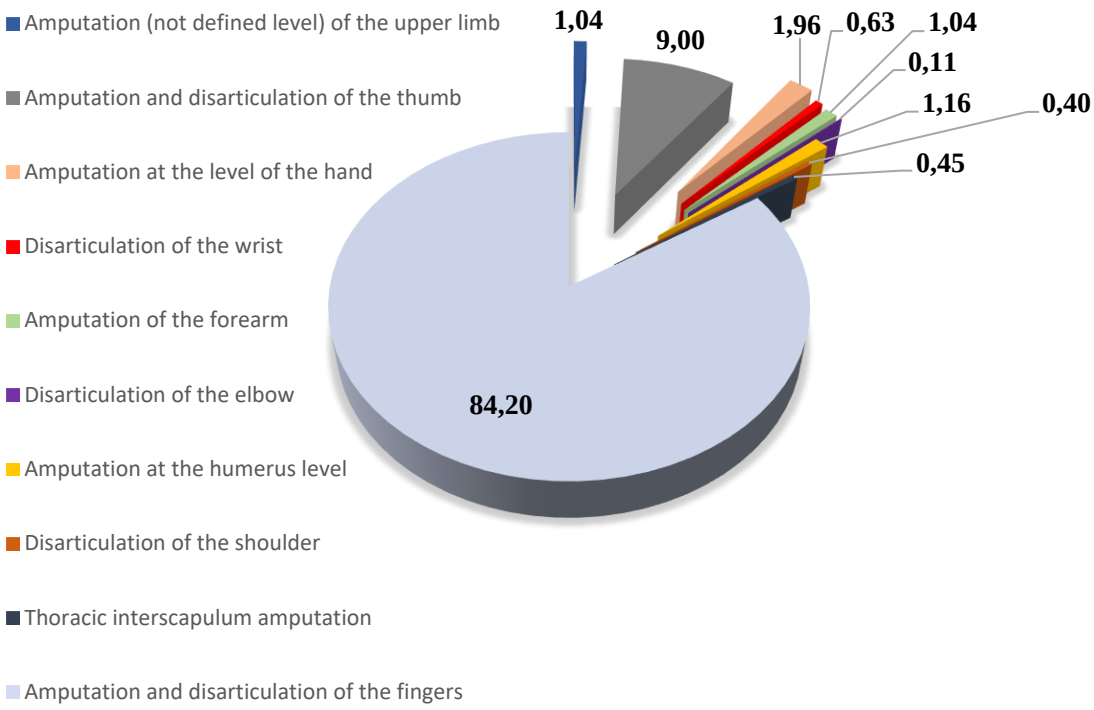


Table 5: *Percentage values of upper limb amputations based on the level.*

The research indicates that the most affected people are new-borns or middle-age persons (50 years old). The tendency of these amputations is downwards. In fact, the number of upper limb amputations is decreased by about the 24% from 2006 to 2013.

For all the previously mentioned levels of amputation, a combination of modular prosthetic devices can be adopted by the amputees in order to replace the missing limb.

1.3 Upper limb prostheses

The aim of a prosthesis is to restore body image and improve functioning, in a cosmetically acceptable way. A prosthesis must possess specific requirements. It has to respond to characteristics of functionality, reliability, little weight and overall dimensions associated to a cosmetic aspect as acceptable as possible. Each commercial prosthesis necessarily must address the CE mark and its related European norm compliancy.

The European norm *EN ISO 9999* establishes a classification of assistive technical aids for people with disability, in order to help them and ease their lives. The terminology "technical aid" identifies every product, including devices, instrument, equipment and software, used by a disabled person:

- For participation
- To protect, support, train, measure or substitute for body functions/structure and activities
- To prevent impairments, activity limitations or participation restrictions

The definition of upper limb prosthesis specifically, found in the norm, is: "*orthopaedic aid that compensate or substitute, although partially the missing limb both on a functional and aesthetic aspect (…) An upper limb prosthesis is a combination of compatible components, usually produced by a single producer and commercially available. The components might be integrated with any other component individually fabricated, to produce a range of different upper limb prosthesis*".

The norm provides two different methods of classification:

1. Depending on the level of amputation.

Code	Description
06 18 03	Prosthetic finger and hand amputation
06 18 06	Prosthesis for wrist disarticulation
06 18 09	Prosthesis for trans-radial amputation
06 18 12	Prosthesis for elbow disarticulation
06 18 15	Prosthesis for trans-humeral amputation
06 18 18	Prosthesis for shoulder disarticulation
06 18 21	Prosthesis for interscapulathoracic amputation

***Table 6**: ISO classification for upper-limb prostheses depending on the level of amputation.*

2. Depending on the construction features, the functional characteristics and the method of control.

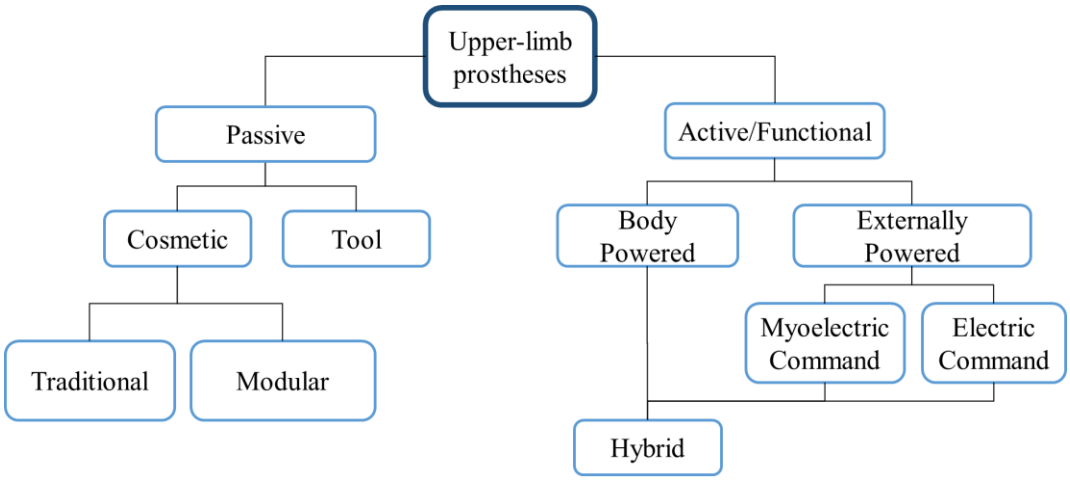


***Figure 23**: Classification of upper-limb prostheses depending by their functionalities.*

Hence, the second classification divides the world of prosthetics into two main families [8]. The major difference between active and passive prostheses is found in the capability of generating force. In active prostheses, this force can be generated to perform grasp tasks, and so they are defined as functional. On the other side, passive prostheses cannot provide force, so they cannot generate any movement. A deeper description of the classification based on the technological features is reported hereafter.

1.3.1 Passive prostheses

Passive prostheses are used to replace, for cosmetic purposes, the missing part of the limb. They consist of prosthetic hands and prosthetic tools which can either be static or adjustable, with no active grasping mechanism. Static prostheses cannot be moved at all, whereas the adjustable prostheses include a mechanism that allows the grasping. Alternatively, they can also possess a physical part which can be adjusted to multiple orientations (excluding the wrist).

Passive prostheses are mostly used by young children and recent amputees, since they are relatively easier to manage and lightweight respect to the active ones, expected to be integrated later. A recent study found out that old people, with a long time-lapse since amputation, are passive prostheses' users, therefore suggesting that, with time, people change from active to passive prostheses [9].

Aesthetic/cosmetic hand prostheses

The cosmetic or aesthetic prostheses (Figure 24) aim to reconstruct the aesthetic aspect of the missing limb, offering a lifelike appearance and recomposing the integrity of the total body image.

Users of these prostheses mostly rank comfort and appearance at the forefront, preferring them in social occasions, as they enhance self-image and self-confidence, with the compromise of a limited functionality. Their advantages are also related to the weight, the design and the ease of use, besides the fact that they can be applied to every level of amputation [10].

The cosmetic hands must satisfy very high aesthetic standards, also in details, regarding the colour of the skin, the natural shape and aspect, and the consistency/rigidity. Usually, they are formed by an internal hand and an external glove, made with silicone, PVC or latex.

Figure 24: *Cosmetic arm prosthesis.*

The aesthetic hand is not merely used for an aesthetic purpose and as a visual substitute of the missing limb, but often it is used as a support for the sound arm, for example to stabilize objects during bimanual tasks. The adjustable aesthetic hands can indeed be passively opened and closed by the sound hand, or the closing system can be actuated by an automatic mechanism that exploits a spring.

In the cosmetic exoskeletal prostheses, also called traditional, the external rigid surfaces have a supporting and structural function. The same function, in the endoskeletal prostheses, is performed by tubular modular internal components, while the external coverage of expanded material is shaped on the residual limb, with an exclusive aesthetic role.

Working prostheses or prosthetic tools

These kinds of prostheses are generally realized for specific purposes, with the aim to facilitate specific activities. This group of prostheses includes devices specifically designed for sport, recreation and vehicle driving.

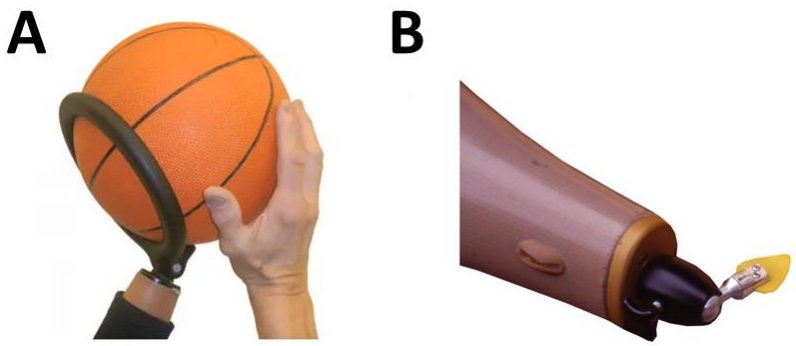


Figure 25: *Prosthetic tools for:* ***A)*** *playing Basketball and* ***B)*** *playing the guitar.*

1.3.2 Active prostheses

The primary aim of active prostheses, also known as functional prostheses, is to substitute and restore the functional characteristics and fundamental movements of the missing limb. Active prostheses differ in the method of application of the external force, which is produced by the grasping mechanism. The three main classes of active prostheses are described in detail in the list below:

Body-powered prostheses

The body-powered prostheses exploit the residual muscles of the stump, or muscles from other parts of the body. Using the mechanical energy produced through cables, activated by braces, these prostheses can perform the movement.

Figure 26: *Body powered prosthesis with two different terminal devices.*

These kinematic prostheses have reduced functionality and comfort, allowing only few movements (opening and closing of the hand, flexion/extension and block/unblock of the elbow). They require a higher energy consumption, leading to fatigue more easily, and can generate a limited prehensile strength. Nevertheless, they are appreciated due to their relative lightness, reliability, robustness, versatility in every environment and sensorial feedback, given by cables and braces. This kind of prostheses are used for amputations under the third medium trans-humeral. Otherwise, for more proximal amputations, actuating levers would be disadvantageous.

Externally powered prostheses

In externally powered prostheses, also known as electromechanical prostheses, the movements are actuated by electrical motors alimented by batteries, whose verse of rotation determines the verse of the movement. They can produce a higher grip strength, minimizing the energy consumption and enhancing the comfort, although their weight and design complexity might be considerable.

Figure 27: *Externally powered myoelectric prosthesis.*

Based on the method of control, they are defined as:

- **Myoelectric prostheses**

  If the subject can activate voluntarily and in an isolate way precise group of muscles, the control may be actuated by surface EMG signals, generated by the isometric contraction of the residual muscles of the limb and collected through surface electrodes.
- **Electronic prostheses**

  Usually, these prostheses are used with sensors of pressure. The method of control is activated by specific switches or slider-type input.

Hybrid prostheses

Hybrid prostheses are basically use for trans-humeral amputees. They constitute the union between the externally powered prosthetic and the kinematic prosthetic, usually including a myoelectrically controlled hand and a body-powered elbow, which is controlled through cables and braces.

***Figure 28**: Hybrid prosthetic solution: a body powered elbow with a myoelectric hand.*

This solution has the advantage of a lower weight while maintaining a good functionality, but it is not always applicable. The length of the trans-humeral stump must be generally higher of the third medium and the shoulder must have a good mobility.

1.4 Myoelectric prostheses

The most advanced prostheses currently existing are the so called “Myoelectric prostheses”. These devices use electromyography signal (EMG), generated from the contraction of the stump’s residual muscules, for the activation of the functional elements of the device. As already said, the application of these prostheses might be possible only if some conditions are satisfied: there must be enough electromyography signals’ availability, with high amplitude, in order to allow the sensors to recognize them, and the capability of the subject to activate independent group of muscles voluntarily.

The signals are recorded by superficial electrodes placed on the skin and usually fixed in the socket, filtered, processed, amplified and converted in command for the motors of the joints, to obtain a functional and natural movement of the artificial limb, following the nervous stimulus of the user. The user can even regulate the strength, the velocity of the movement and the grip of his prosthesis by varying and finely controlling the intensity of his contraction.

1.4.1 Control strategies

There are four main types of myoelectric control currently implemented, which can be used for the myoelectric prosthetic hands. All of them use surface electrodes, integrated in the socket:

One site - Direct control

In this control strategy the developed strength is predetermined. It indeed implements the “all or nothing” rule, so the velocity of the contraction is always unaltered, even with muscle signals of different intensity.

Thus, the grip strength does not depend on the duration of the muscle signal but, instead, it is device dependent. The movement (i.e. closure) of the device is actuated by the activity of a single group of muscles (flexors or extensors). The counteracting movement (i.e. opening) is automatically implemented on hardware or software and it is based on a “virtual” spring load mechanism. So, for example, the closure is *directly* controlled based on the single EMG signal, whilst the opening is automatically performed as soon as the contraction ends, or viceversa.

One site – Proportional/Dynamic Mode Control (DCM)

This strategy, as the previous one, works by means of only one electrode. The command is proportional to the strength of contraction; grip speed and grip force are determined by the intensity of the muscle activity. The counteracting movement is automatically implemented on hardware or software and it is based on a "virtual" spring load mechanism. So, in this case, the closure is *proportionally* controlled based on the single EMG signal's amplitude, while the opening is automatically performed as soon as the contraction ends or goes below a certain threshold, or vice versa.

Dual sites - Proportional/Dynamic Mode Control (DCM)

This method is used to proportionally control different movements (i.e. opening and closure) or prosthetic components (hand and wrist by means of co-contraction strategy), exploiting a couple of electrodes.

Coherently to the co-contraction approach, other existing switching mechanisms such as through buttons/switches, vocal commands or app on the smartphone, have low intuitiveness and hence they are not so appreciated by users.

Although the previously mentioned strategies offer a poor intuitive control, these are the most used in the everyday life.

Multi-channel – Direct or Proportional Control

When the number of active degrees of freedom increases, the co-contraction control strategy lacks in promptness. The most intuitive control existing in prosthetic is based on artificial intelligence algorithms, known as *pattern recognition*. It is, in fact, the latest control introduced on the market. It uses up to six EMG electrodes and it is focused on identifying a pattern of muscles contraction and in their mapping into a specific movement of the entire device. Although it is capable to offer the most natural and intuitive control strategy currently on the market (Ottobock and Coapt, LLC), it is not robust enough to be frequently used by patients.

1.4.2 Commercially available polyarticulated prostheses

The human hand offers a very high number of functionalities and degrees of freedom, making the development of a complete prosthetic hand (and hence its related prosthetic system) as much as similar to the natural one very challenging. The existing technology is indeed still not able to provide a unique solution capable to recreate all the possible movements of the hand [11].

Currently, two main categories of myoelectric prosthetic hands can be found on the market: the so called "tridigital hands", simple devices with high responsiveness thanks to their single DOF (the contraposition of thumb and index/medium), low cost and lightweight but, at the same time, poor in term of anthropomorphic features [12], and the so called "poly-articulated prostheses", in which high tech actuators, high precision of movement and human likeliness have been prioritized, with the drawback of a very high cost [13], [14].

The latter offer an active movement of all the five digits, producing a more natural and fluid motion which, together with a glove in PVC or silicon, provide a realistic and great aesthetic aspect.

The two main competitors on the market, for what concern the myoelectric poly-articulated hands, are Ossür, with the **i-Limb Quantum** hand, and Ottobock, with the **Michelangelo** and **Bebionic** hands [15].

i-Limb Quantum - Ossür

In the i-Limb Quantum prosthetic hand, the embedded gestures control allows the user to automatically change the grip mode. This mechanism is activated by moving the device in one of the four available directions. Every digit is individually powered by a motor, which performs the entire range of motion until the object is grasped and has the capacity to stay motionless. The fingers are not singularly controlled, but the automatic grips let the user disable certain digits and move the remaining to hold an object or to perform a gesture. The prosthesis permits the realization of 24 pre-programmed grips and 12 customizable ones. The interphalangeal distal articulation is missing, so the more distal phalanx is fused with the second one. The thumb, with an electronic rotating system, automatically alternates the lateral and opposable handle models. The prosthetic hand might be provided of a wrist with an active pronation and supination module.

***Figure 29**: i-Limb Quantum by Ossür.*

Michelangelo - Ottobock

The long fingers of the Michelangelo prosthetic hand at the metacarpophalangeal articulation level move in synchrony. The index and the medium are the main responsible of the generated grasp strength. The thumb articulates at the carpometacarpal articulation level, with active motions both in flexion-extension and abduction-adduction. The total complexity permits to implement seven different grips. The palm contains the electronics of the hand and the single motor responsible for the movement of flex-extension of all the digits, and so for the generation of the grip strength. A second motor is positioned inside the phalanx of the thumb itself, regulating the grade of abduction-adduction, without contributing to the developing of the grip force. The fingers are not parallel, and they open with a rake mechanism. The prosthetic hand might be provided with or without a wrist with active pronation-supination.

***Figure 30**: Michelangelo by Ottobock.*

Bebionic - Ottobock

This prosthetic hand presents fourteen different type of grips (even if usually only four or five are used) through a lead screw mechanism connected to a four-bar linkage placed in every digit, triggered by an electric motor custom-made positioned in the palm. The interphalangeal distal articulation is not present, so the distal phalanx is combined with the middle one. The distal articulation of the thumb is active. The distal phalanx is articulated and connected by means of another four-bar linkage with the proximal one, providing an active flexion and extension. On the other hand, the abduction-adduction movement is purely passive.

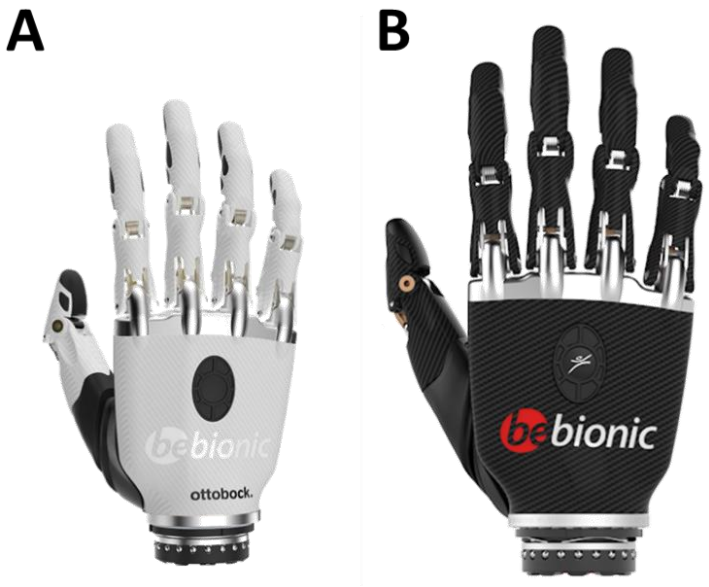


***Figure 31**: Bebionic hands: **A)** small size and **B)** medium size by Ottobock.*

1.5 Pre-market clinical evaluation with *Hannes*

This research activity is based on the evolution of a previous clinical trial, defined as a pre-market clinical evaluation with the novel *Hannes* system. The *Hannes* prosthetic hand (deeply described in Chapter 2.1:The *Hannes* system) was developed by the Rehab Technologies Laboratory (Istituto Italiano di Tecnologia), from 2014 to 2017, and has obtained the CE mark at the end of its development phase in 2017.

The post-market clinical trial on which this research is based on has been developed making reference to this pre-market clinical trial. After noticing and observing the limits of this clinical evaluation a more robust clinical protocol has been designed, with the main objective to evaluate the Embodiment. The concept of Embodiment is discussed hereafter in Chapter 1.6: Embodiment, whilst a deep discussion of the post-market clinical trial will follow in the Chapter 2.2: Pre-validation of the post-market clinical trial.

Pilot trials on amputees were performed to evaluate the effectiveness and usability of *Hannes* [16] with respect to the reference prosthesis for each patient (Michelangelo, Variplus and Variplus). Tests and questionnaires were conducted before and after about 2 weeks of daily home use of *Hannes*. Moreover, experiments were assessed to validate the high performance and the human likeness of the grasping behaviour.

1.5.1 Methodology

The evaluation was performed on three male patients with a transradial amputation of the right arm, experts in the use of myoeletrically controlled prostheses. Tests and questionnaires specifically designed to measure prosthesis use ability were exploited. First, these procedures were conducted on the reference hand (**TB**), then on *Hannes* before the 2 weeks of training time (**T0**), after them (**T1**), and at the end of this study (**T2**). The questionnaires were presented at **TB** and **T2**.

Two functional validated tests were used:

- The *Minnesota Manual Dexterity Test (MMDT)* is an internationally validated test which measures the time spent to move a set of small objects [17]. Precisely, only the Placing task was administered (MMDT-P). In this task the objects must be placed, starting from the corner corresponding to the amputated side (in order not to invade and obstacle the field of view of the participant), one column after another in a board below, from the top to the bottom. The score is the time required to complete the task.

- The *Southampton Hand Assessment Procedure (SHAP)* is a clinically hand function test. It assesses the effectiveness of upper limb prostheses [18]. It is made up to 6 abstract objects, heavy and light, which permit 6 different grips, and 14 Activities of Daily Living (ADLs). Each task was timed by the subject.

Three validated qualitative questionnaires were administered to the three subjects, investigating the independence of the user in the execution of ADLs:

- The *Orthotics and Prosthetics User Survey Upper Extremity Functional Status (OPUS-UEFS)* questionnaire evaluates functional activities performed by amputees with a prosthesis [19].
- The *Disabilities of the Arm, Shoulder, and Hand (DASH)* questionnaire measures the level of impairment in functional activities of the upper limb, with scores ranging from 0 (functional activity like in a natural hand) to 100% (no function at all) [20].
- The *Trinity Amputation and Prosthesis Experience Scales (TAPES)* questionnaire investigates the degree of satisfaction in the usage of a prosthesis [21].

Moreover, at **T2**, a final evaluation questionnaire was administered.

1.5.2 Results and Discussion

Table 7 provides the results of the three participants obtained with the commonly used hand during the baseline assessment (TB) and with the *Hannes* system during the study (T0, T1, and T2).

	Subject 1					Subject 2					Subject 3				
	TB	T0	T1	T2	T2 – TB	TB	T0	T1	T2	T2 – TB	TB	T0	T1	T2	T2 – TB
Minnesota score [s]	137.33 ±15.31	132 ±6	125.33 ±8.08	123.67 ±4.04	-13.66	171.67 ±10.07	181.67 ±20.50	142.33 ±6.43	133.67 ±6.03	-38	140.67 ±10.50	210 ±20.30	171 ±38.74	166.33 ±10.07	26.66
SHAP (IoF [%])	76	78	71	74	-2	72	66	77	76	4	58	43	62	61	3
Spherical [%]	79	82	77	77	-2	74	82	90	88	14	75	57	76	76	1
Tripod [%]	63	70	60	70	7	44	35	44	53	9	29	24	49	50	21
Power [%]	75	77	65	71	-4	59	53	59	66	7	52	42	57	63	11
Lateral [%]	85	75	73	72	-13	77	68	80	83	6	70	34	58	55	-15
Tip [%]	60	68	65	63	3	70	58	70	65	-5	45	30	55	51	6
Extension [%]	75	78	70	76	1	71	66	78	80	9	67	44	61	69	2
OPUS-UEFS															
Score [%]	96.05	x	x	80.36	-15.69	86.76	x	x	82.5	-4.26	67.5	x	x	88.75	21.25
Usage [%]	67.86	x	x	50	-17.86	60.71	x	x	71.43	10.72	74.07	x	x	71.43	-2.64
DASH															
ADLs [%]	0.8	x	x	2.5	1.7	2.5	x	x	2.5	0	4.3	x	x	10	6.7
WORK [%]	0	x	x	0	0	-	x	x	-	-	0	x	x	18.8	18.8
SPORT [%]	0	x	x	0	0	0	x	x	0	0	-	x	x	-	-
TAPES															
Score [%]	98.3	x	x	93.1	-5.2	88.3	x	x	90.8	2.5	74.1	x	x	76.6	2.5
Final Evaluation															
score	-	-	-	8/9	-	-	-	-	7/9	-	-	-	-	4/9	-

Table 7: *Scores of tests and questionnaires.*

Figure 32 shows the improvement/deterioration in tests and questionnaires scores from the baseline to the end of the study by reporting the percentage difference between the scores recorded at T2 and the scores recorded at TB.

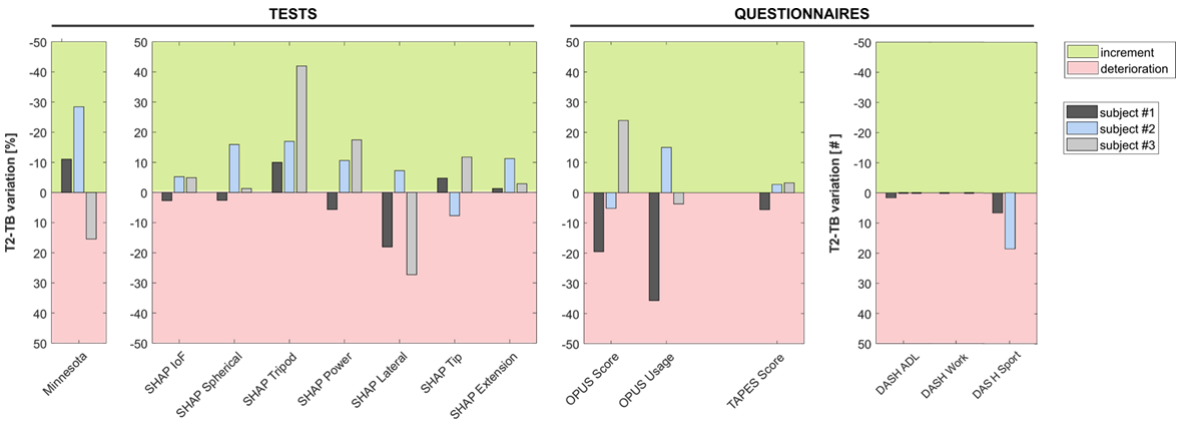


***Figure 32**: Rate of improvement of tests and questionnaires' scores.*

The MMDT-PT results were, on average, better with *Hannes* with respect to the commonly used prosthesis. Participant #1 and #2 improved their times with *Hannes* of about 10 and 30% respectively (T2 vs TB), while participant #3 needed more time to perform the task with *Hannes*, compared to his results in TB with the reference hand, as shown in Figure 32 (note that for the Minnesota test, negative values indicate an improvement and positive values indicate deterioration). This result can depend on the fact that, differently from the two other amputees, the user #3 was not a poly-articulated hand user. He only had experience with tridigital hand. This confirmed that a training period of 2 weeks is insufficient to shape neural plasticity in order to incorporate the new prosthesis into body representation [22]. However, excluding the initial performance, all subjects showed an improvement during the training period (from T0 to T2, Table 7).

Similar results were collected with the SHAP test. The scores at TB and T2 were comparable and, in several cases, there was an improvement from TB to T2 (see Figure 32). A technical issue caused critical results in the lateral grasp for participant #1 and #3, but it was solved after the trials with a mechanical fix.

In addition to these functional tests, the questionnaires provided a qualitative evaluation of the usage of the prosthesis during ADLs, given at TB and T2.

In the OPUS-UEFS questionnaire, as shown in Figure 32, participant #1 reached higher scores with the reference hand, while participant #2 and #3 showed an improvement with the use of *Hannes*.

In the DASH questionnaire participant #1 and #2 performed better with their common prosthesis, while participant #3 found the level of functionality not changed. Since the DASH scores cannot be represented with a percentage, the difference between the scores at T2 an TB are reported in Figure 32 (note that for the DASH, negative values indicate an improvement and positive values deterioration).

The TAPES questionnaire showed a preference towards *Hannes*, with respect to the reference hand, for participant #2 and #3, as the scorings improved by 3 and 5 points respectively (Figure 32). Participant #1, instead, achieved little higher score with the common prosthesis.

Finally, a great appreciation regarding the novel prosthetic system *Hannes* by participant #2 and #3 emerged with the final evaluation questionnaire (Figure 33).

	Subject #1	**Subject #2**	**Subject #3**
Did you use Hannes as frequently as your usual prosthesis?	Yes	Yes	Yes
Any functional difference in ADLs with respect to your prosthesis?	Yes	Yes	No
Is Hannes comfortable for all-day use?	Yes	Yes	Yes
Was battery charge sufficient?	No	No	No
Did you feel faster during task execution while using Hannes?	Yes	Yes	No
Do you think that Hannes might improve execution of ADLs?	Yes	Yes	No
Are you satisfied with the functionality of the Hannes system?	Yes	Yes	Yes
Are you satisfied with the aesthetic of the Hannes system?	Yes	No	No
Is the weight of Hannes acceptable?	Yes	Yes	Yes

Figure 33: *Final evaluation questionnaire.*

1.6 Embodiment

The loss of a limb is a tragic event, leading to a serious impairment in the everyday life, in the operational functionality as well as to psychological and psychosocial negative effects. Losing a limb has devastating different consequences: the amputee is no longer able to perform his usual daily activities, he is not completely autonomous and independent, and this results in a dramatic decrease of the quality of life [23]. The absence of an upper limb irreversibly changes the look and affective interactions of the amputee, causing severe repercussion such as social rejection, self-pity, low self-esteem [24].

The hands are the primary tool of the brain, and the loss of a hand leads to profound changes in individuals' abilities to interact with their environment. The strategy for adapting to hand loss is using an artificial upper limb, a prosthesis. A prosthesis is, therefore, an assistive device which should become an essential companion for the entire life of the amputee.

Current prosthetic options range in both cosmetics and functionality, to satisfy a variety of user needs and lifestyles. Even with the new available technology, the level of functional restoration is considered poor. When more than one degree of freedom is actuated, the method of control is not natural and easy to be implement. The patient must learn to enforce a sometimes-complicated sequence of muscles contractions to switch the control among the different available degrees of freedom. For this and other reasons such as weight, cost, maintenance, repeated mechanical failures, reliability, absence of feedback and complexity of control, myoelectric prostheses are not preferred by amputees with respect to cosmetic and passive prostheses. The abandonment rate is, indeed, still high. A large part of the amputees' population even prefers not to use any prosthesis at all during their daily life [25].

Prosthetic rejection is also associated with the development of one-handedness, the presence of residual limb and its related phantom pain, limitations in flexibility, strength, endurance, and mobility. Regular prosthetic use may help amputees avoid future cumulative trauma disorders in the sound-side limb, as well as neck and back pain, related to compensatory strategies, which are commonly reported [26].

Only the 45% of all arm amputees choose to use their prosthesis regularly [27].

Broadly speaking, upper limb amputees are hardly satisfied with their prostheses and tend to favour the use of the contralateral arm to partially compensate their disability.

Beside the list of specific technological issues described by patients about the abandonment and rejection of prostheses' usage already discussed, a popular assumption is that amputated people reject prostheses because they do not feel the device like a real body part and hence, "embodied".

The problem is the sensorimotor challenge to embody a prosthetic limb.

With the term "Embodiment" is meant the incarnation and integration of an external and foreign object in the internal corporal scheme, as if it was part of the body itself. In this specific context, the external object is, precisely, the prosthesis [28].

Embodiment has been suggested to promote intuitive control, learning and comfort when using new tools, thus providing the opportunity to improve the user interface for devices such as artificial limbs. Embodiment is a compound phenomenon, which involves two different levels [29] [30]:

- features that belong to an explicit level, including explicit feelings such as bodily ownership, bodily control, bodily integrity, answering for example to questions like "does the artificial limb feel like my hand?".
- features that belong to an implicit level, regarding body representations and questions like "do I react with the artificial limb as I would with my own hand?".

Embodiment comprises three correlated factors: ownership, localization and agency [31]. The sense of *ownership* is perceived when experiencing the body as a single whole. *Localization* is the assumption of where the body exists in the surrounding space. The *agency* takes place when sensory predictions and sensory experiences match, leading to a feeling of control over actions and the resulting impact on the environment around. Agency is highly related to prosthetic usage because it depends on sensory information and certainty of control, elements that, if absent or low, contribute to prosthesis rejection. In fact, increasing the sense of control might improve prosthesis acceptance.

1.6.1 Embodiment evaluation

There is currently little empirical evidence showing that embodiment actually relates to everyday behaviour with artificial limbs, furthermore there are not international validated and standard tests, scales or questionnaires capable to objectively measure the level of embodiment of a prosthesis. Only some questions are considered standard and frequently used in questionnaires.

The evaluation of the embodiment is not an easy task to accomplish, due to its non-physical nature. The most commonly used instrument to evaluate and investigate embodiment is through questionnaires. However, the subjectivity in self-report questionnaire response system can introduce bias, inter-individual differences and limit comparison of results. Quantitative and objective investigation through more implicit measure, such as spontaneous actions, would allow unbiased data analysis and a better comparison.

Other ways to investigate and evaluate the embodiment have been developed and tested recently.

The study of Imaizumi [32] shows that an embodied prosthetic arm can stabilize amputees' body posture and improve body balance. A frequent use of the prosthesis allows reduction in postural sway when wearing the prosthesis, while larger sway is showed without it. The study suggests that frequent prosthetic arm users, indeed, might have incorporated their devices into their own body representation, increasing the embodiment, and consequently involving them in the feedback/feedforward postural control system of the whole body.

An implicit measure of embodiment has been proposed by the study of Maimon-Mor [29]. Focusing on the fundamental role that hands play in human life, communication, the researchers tried to measure the embodiment through hand gestures, finding that prosthesis functional daily usage and perceived embodiment are significantly correlated.

Many studies regarding the embodiment have involved the peripersonal space, the manual movement (Fraser, 1984) and the proprioception (McDonnell et al., 1989).

It has been demonstrated that amputees perceive an increased length of the stump while wearing the prosthesis, extending the peripersonal space boundaries to include the prosthetic hand [33].

The study of Gouzien [30] investigated the implicit body representation by evaluating the peripersonal space with a reachability judgement task in correlation with the bodily

integration of the patient's prosthesis. As predicted, the subjects estimated that they could reach further while wearing the prosthesis, evidencing the embodiment of the device in their judgment.

A more invasive measure of embodiment has been proposed, investigating if an artificial limb is embodied as a hand through brain decoding. Using functional Magnetic Resonance Imaging (MRI), the study of Fiona M. Z. van den Heiligenberg [34] showed that the more an amputee uses his artificial limb in the everyday life, the stronger visual hand-selective areas, in the lateral occipitotemporal cortex, respond to prosthesis images. Furthermore, daily prosthetic usage results in larger inter-network communication across hand-selective areas. Findings suggest that altered daily motor behaviour facilitates prosthesis-related visual processing and shapes communication across hand-selective areas, showing a neurophysiological basis for prosthesis embodiment.

Novel approaches to evaluate the Embodiment are always under investigation. The final goal is to provide an effective methodology able to measure this untouchable phenomenon, preferably with objective and comparable results.

1.6.2 Embodiment stimulation

Beside the evaluation of the level of embodiment, it is of great interest also studying how to stimulate it, in order to improve the prosthesis acceptance and integration in the corporal scheme of amputees, therefore increasing the usage of it and the quality of life.

Embodiment has been demonstrated to be affected by sensory feedback. The absence of sensory feedback in the current available prostheses is cited as one of the reasons for the rejection of prosthetic hands, forcing the user to constantly give visual attention to his artificial hand and to maintain a very high mental concentration.

Prior studies have used a common experimental paradigm, the **Rubber Hand Illusion** (RHI), to arise the sense of embodiment [35], [36]. By applying synchronous stimulation and matched stimuli to a rubber hand and to the participant's own hand, hidden from view, it was demonstrated that the sense of body ownership is closely associated with cutaneous touch [37].

A similar methodology can be applied to amputated people to elicit embodiment of artificial limbs. An amputation leads to sensory reorganizations due to functional changes in cerebral cortical maps of the body. This often allows to find in the stump of the amputee a mapping of the phantom limb and specific areas corresponding to the phantom digits. A modified RHI with vibrotactile stimulation can improve the embodiment of external devices. Tricking the amputee with synchronous stimuli to the stump and to the prosthesis (even with a mismatched modality) creates a vivid illusion of ownership and connection between the body and the passive prosthetic hand [38]. Furthermore, adding remote active control of the robotic hand has been shown to enhance the experience of the RHI [37].

Recent advancements and developments in technology have allowed to create very immersive **Virtual Reality Environments** (VREs) for a rehabilitative aim, where several performances and behaviours can be trained and learnt. VREs can be used, for example, for treating phantom limb pain, designing and simulating the use of prosthetic devices before fabrication, for training the control of the artificial limb through a virtual prosthesis and, simultaneously, enhancing the embodiment of the robotic hand [39].

By exploiting this new technology, it is possible to implement a **Virtual Hand Illusion** (VHI), inspired by the original rubber hand illusion paradigm. In this paradigm, participants experience the perception of owning a virtual hand as part of their real bodies.

This trial stimulates the three main sub-components of embodiment, already cited before: the sense of ownership, feeling that the virtual body is part of the real body; the sense of agency, feeling personally responsible for controlling the virtual body; the sense of self-location, feeling the real body positioned in continuity with the virtual body. In the virtual hand illusion, the embodiment is accomplished by giving the brain some congruent synchronous visual, motor, tactile or proprioceptive information regarding the virtual body, resolving sensory conflict and leading to the integration of the virtual body as part of the real body [40]. The illusion can also be strengthened improving the anthropomorphic characteristics of the virtual body and the level of visual realism, as well as providing visually connected, and so more realistic, hands with forearms. Anyway, it has been demonstrated that the ability to control the virtual body is more relevant than the appearance of the hands [41].

It is thereby possible to stimulate the embodiment of artificial external tools by implementing the aforementioned criteria in a custom-made VR environment. Especially when the implemented tasks are not static, the real-time interaction of the subject with the virtual environment plays a key role in enhancing the embodiment perception.

Researchers work to develop always better methods capable to evaluate the increasing functionality of the newest prostheses. Other methods under design have the goal to quantify how much the users appreciate their devices, considering them as real efficient substitutes of their missing limb. The attention is increasingly shifting to the users' point of view with a deep investigation in the process of Embodiment of artificial limbs. The focus is hence toward its evaluation and, furthermore, its stimulation.

In conclusion, this Chapter of the State of the art provides a general vision of the condition of upper limb amputation, presenting the uniqueness and complexity of the lost organ from an anatomical and biomechanical point of view. The fundamental role played by the hands in the daily life has been widely proved, evidencing the disability (both functional and psychosocial), to which the loss of them brings. The adoption of a prosthesis is used to compensate this condition. Several kinds of prostheses, addressing different needs, have been discussed. The latest poly-articulated hands prove that the technology is under a continuous state of development, with the aim to always do better in order to decrease the prosthesis abandonment rate.

2 Materials and methods

In this Chapter, Materials and methods of this study are discussed and explained. First, the device under investigation is presented: the *Hannes* prosthetic hand.

Hannes was designed to fill the gap between the two extremis of electromyographically controlled devices: the "tri-digital hands", very simple devices (very low cost and lightweight but at the same time poor in term of anthropomorphic feature) and the "poly-articulated ones" (where high-tech and human likeliness has been used with the drawback of a very high-cost devices), as shown in Figure 34.

Hannes has been developed in order to be coherently definable as a low-cost hand but, at the same time, capable of providing performances and aesthetics very comparable with the high-tech ones.

Figure 34: *Market positioning of Hannes with respect to the currently on the market prostheses.*

Second, the methods of this study are discussed accordingly to their main subdivision:

- the first section of this work is focused on the ***pre-validation of the post-market clinical trial*** (described in Chapter 2.2: Pre-validation of the post-market clinical trial). The pre-validation was based on a wider official clinical trial accepted by an Ethics Committee. It aimed to evaluate the user experience (UX), the embodiment and the functionality reached by three *Hannes* users, with a three-month follow-up, with respect to their commonly used prostheses. The trial comprised functional and embodiment tests, together with questionnaires which investigated all the three main components of the pre-validation (UX, embodiment, functionality).
- the second section regards the ***feasibility pilot study exploiting a spatially augmented Virtual Reality to stimulate the embodiment of a virtual prosthesis*** (described in Chapter 2.3: Embodiment stimulation – a pilot study). The feasibility study investigated if the respiratory rhythm was able to influence the embodiment of a virtual hand. The assumption was that a slow forced respiratory rate, with respect to a normal one, could induce a psychophysiological state which facilitated the embodiment. The research had a "within-group design": each subject was indeed tested with all the two different conditions. The embodiment evaluation was obtained through a subjective questionnaire and the measurement of a proprioceptive drift. The reason behind this exploratory study is the creation of a "rehabilitative virtual training tool" capable of stimulating the embodiment of a prosthesis.

2.1 The *Hannes* system

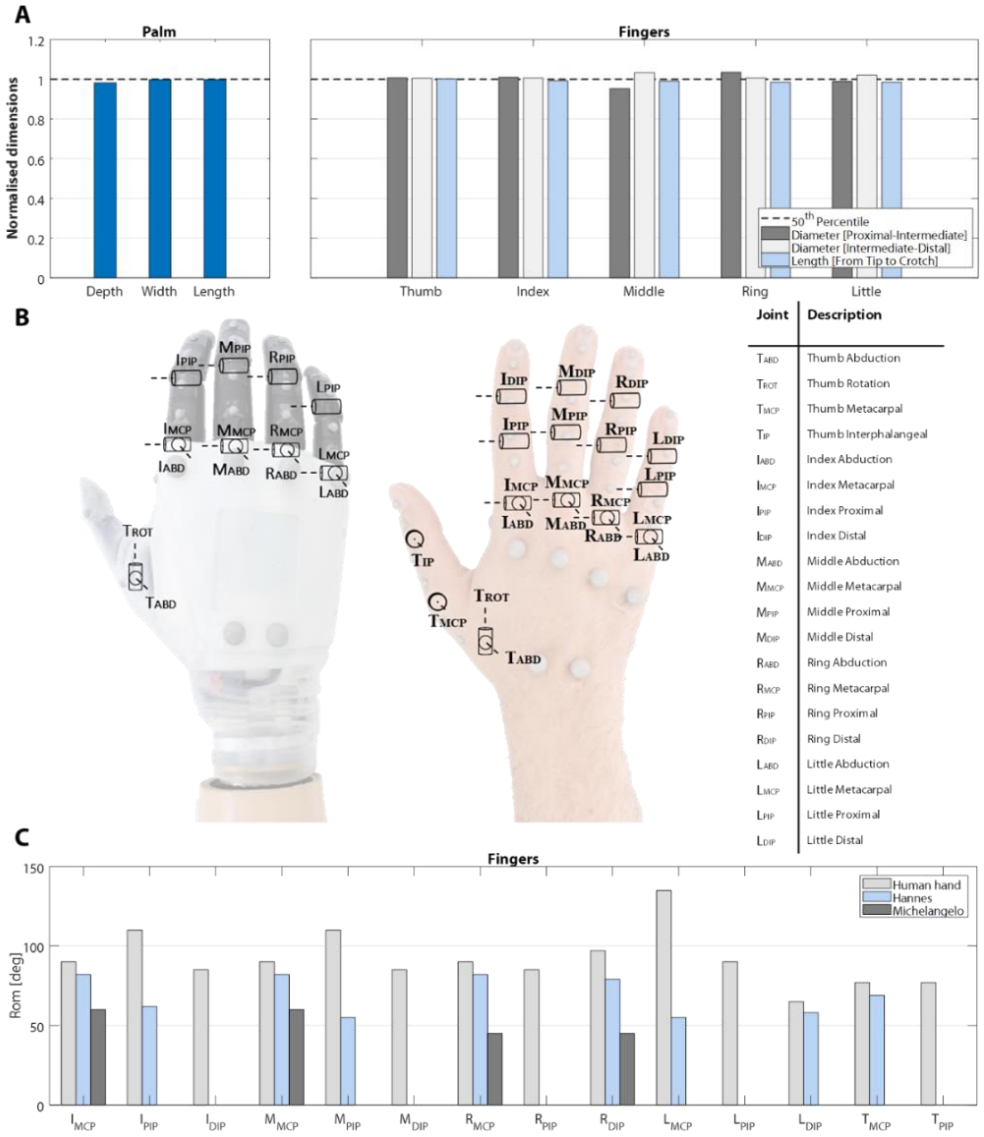
The *Hannes* hand prosthesis was developed during a three-year collaboration (January 2014 – December 2017) between the Rehab Technology Laboratory of Istituto Italiano di Tecnologia (IIT) and Istituto Nazionale Assicurazione Infortuni sul Lavoro (INAIL). The device is a poly-articulated prosthetic hand able to restore over 90% of lost functionality in people with upper limb amputation. *Hannes* is the result of a holistic design approach which involved an extensive co-development activity between researchers, patients, orthopaedists, and industrial designers. The major improvements provided by this device with respect to the currently on the market ones are the naturalness of forms, movements and orientation of the rotation axes and hand posture. *Hannes* integrates key biometric properties that make this prosthesis extremely and uniquely similar to the real human hand [16]. The prosthetic design was developed focusing on the anthropometry of the real human hand, both from an aesthetic and structural point of view, allowing the user to perceive the device as an integral part of the body rather than a simple external tool. An iterative design process was exploited to incorporate mechanics and electronics into the hand's forms and proportions.

Figure 35 shows the timeline of all the *Hannes* prototypes and its transformation towards the last model, with a more human like shape and aspect, a reduced encumbrance and improved materials.

***Figure 35**: The chronological evolution of Hannes from 2014 to 2017.*

The prosthetic hand incorporates high levels of biomimicry through the concomitance of anthropomorphism, performance and functionality, permitting *Hannes* to perform better than other currently available research and commercial prosthetic devices, as proved in Chapter 1.5: Pre-market clinical evaluation with *Hannes*.

The high biomimetic anthropomorphism reached in *Hannes* is shown in Figure 36 with a direct comparison of size, shape and kinematic model of the standard human hand and the Michelangelo prosthesis, used as a gold standard. Precisely, in Figure 36 B it is possible to appreciate the fingers design. All fingers' Degrees Of Freedom (DOFs) were implemented except for the distal interphalangeal (DIP) joint, reproduced with a fixed angle because of a design trade-off between mechatronic integration and functionalities. The thumb has both the middle metacarpal (MCP) and the interphalangeal (IP) joints locked. As shown in Figure 36 C, except for the locked DIP joints, the Range Of Motions (ROMs) of *Hannes* are overall similar to the ones of the real hand and considerably better than what Michelangelo hand proposes.



Joint	Description
T_{ABD}	Thumb Abduction
T_{ROT}	Thumb Rotation
T_{MCP}	Thumb Metacarpal
T_{IP}	Thumb Interphalangeal
I_{ABD}	Index Abduction
I_{MCP}	Index Metacarpal
I_{PIP}	Index Proximal
I_{DIP}	Index Distal
M_{ABD}	Middle Abduction
M_{MCP}	Middle Metacarpal
M_{PIP}	Middle Proximal
M_{DIP}	Middle Distal
R_{ABD}	Ring Abduction
R_{MCP}	Ring Metacarpal
R_{PIP}	Ring Proximal
R_{DIP}	Ring Distal
L_{ABD}	Little Abduction
L_{MCP}	Little Metacarpal
L_{PIP}	Little Proximal
L_{DIP}	Little Distal

Figure 36: *Anthropometry of Hannes:* ***A)*** *Dimensions of Hannes and comparison with the 50th percentile human hand,* ***B)*** *kinematic model and nomenclature of Hannes and the human hand,* ***C)*** *Range of Motion of the 50th percentile respectively of human hand, Hannes and Michelangelo prosthesis.*

The human-like synergistic behaviour of *Hannes* was evaluated by means of a kinematic analysis. The static and dynamic behaviour of *Hannes* was investigated with a direct comparison of postures, correlation patterns, synergies and their combination while grasping different objects of the human hand. In Figure 37 A and B show the static postures of *Hannes* and the human hand respectively while holding 9 distinct objects. At a first glance it is already appreciable how *Hannes* behaves similarly to the human hand.

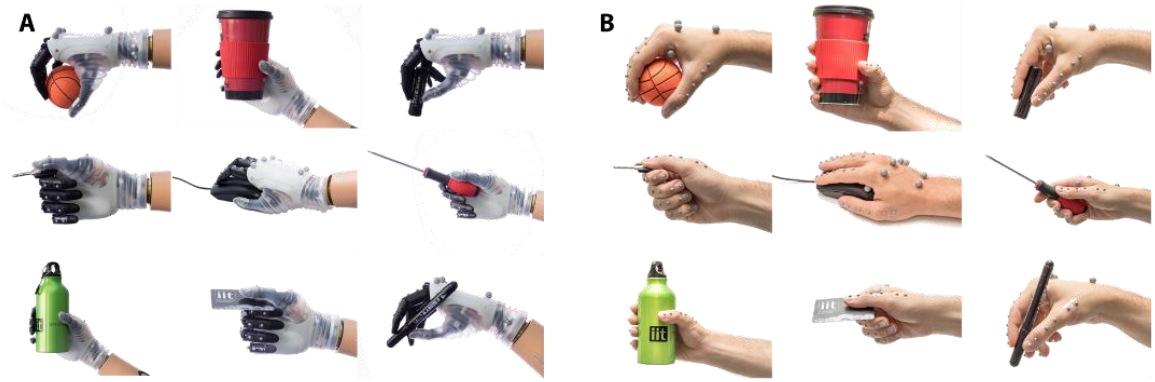


Figure 37: *Static kinematic behaviour of Hannes compared to the human hand:* ***A)*** *static postures of Hannes holding 9 different objects,* ***B)*** *static postures of the human hand holding 9 different objects.*

2.1.1 Mechatronics integration

The palm of *Hannes* contains four main components: an electric actuator, a control board, sensors and the transmission mechanism (Figure 38). The Flexion/Extension flexible wrist is separately placed at the base of the prosthetic hand. The power train is made of a compact, high-power density Direct Current (DC) motor coupled to a custom-made hypocycloid gearbox. The embedded transmission mechanism is the main novelty provided by the *Hannes* hand. It consists of a tendon-driven differential mechanism capable to pull the master wire as well as the two slaves wires in order to properly offer the patient a quick and precise grasp. In particular, the power train drives the leader wire, transmitting the force and the speed to the cable-based mechanism placed in the palm. The master wire begins in the motor and ends in the thumb. It passes through two differential elements fitted on linear guides: liner guides. Each guide is made of a custom-made bush bearing and two rails along which the bushing moves. Each bushing contains two idle pulleys: one pulley supports the leader wire, whilst the second one is used by the follower wire to actuate two adjacent fingers. In order to move all the four fingers, there two follower wires cooperate by means of the master wire as shown in Figure 38. The first one is used to actuate the index and middle fingers, while the second one permits the movement of the ring and little fingers. Springs operating on the linear guides are added to prevent slacks on the leader wire. In this way, all the five digits moves with a synergetic behaviour. This system represents the

differential underactuated mechanism at the base of the Dynamic Adaptive Grasp (DAG system), zoomed in Figure 38. It allows the prosthesis to adapt to the grasped object's shape and to resist to any external disturbances. Regardless the position of the fingers, the same traction force is applied to each digit thanks to this embedded differential mechanism. This underactuated differential drive mechanism is hence the peculiarity that distinguishes *Hannes* from any other type of prosthetic hand, giving human-like grasping properties, such as robustness, stability and synergistic coordination of the fingers.

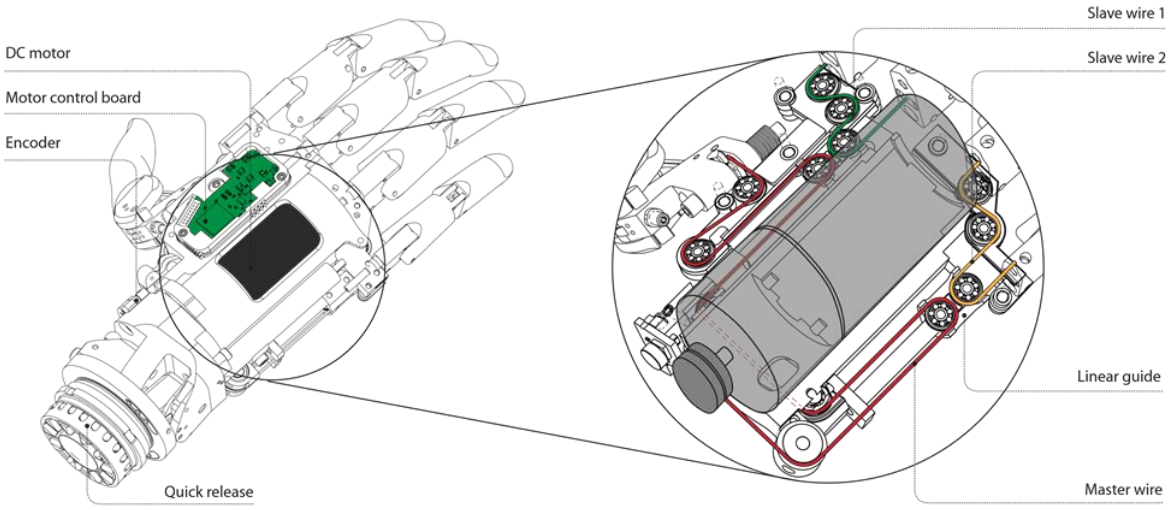


***Figure 38**: The DAG system of Hannes.*

The mechanism of the fingers relies on dowel pins which guide the wires and maximize the robustness (Figure 39 A). The follower wire is placed in the ventral part of each finger, coming from the corresponding linear guide and ending in the distal phalanx. The return wire is located in the dorsal side and it is used for the extension of the finger by means of a linear spring embedded on the distal extremes of each finger. These latter produce a traction force that increases with the flexion of the finger. A pre-tensioning mechanism is also embedded on the other extreme of each finger to properly preload the return wire (and its related spring) and hence to properly calibrate the angular velocity of each finger. When the motor applies the torque, the follower and slave wires go in traction and the extension spring is compressed by the return wire. When the motor unwinds the leader wire, the follower wire slackens and it generates the extension of the return wire and its related spring. This causes the natural fingers' extension.

The closure of the thumb is synchronized with the other fingers through a screw-based mechanism that works on the corresponding return wire (Figure 39 B).

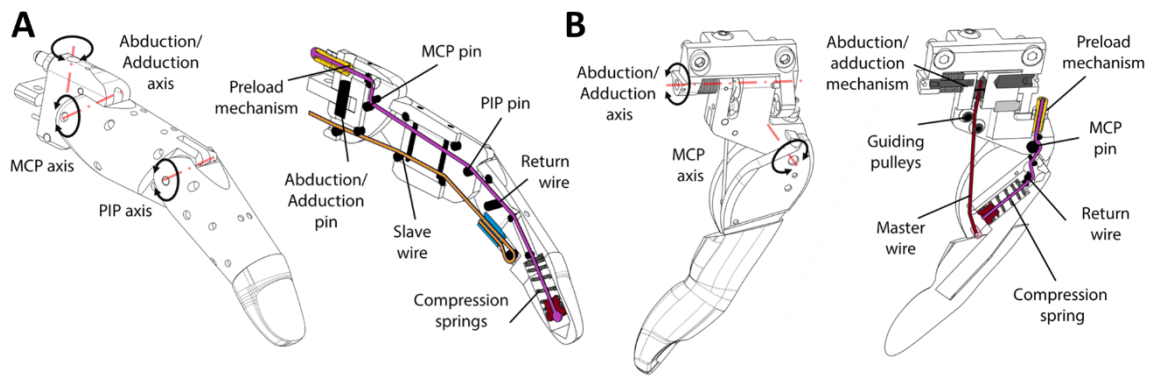


Figure 39: *Mechatronics description of* ***A)*** *fingers (index, middle, ring, little) and* ***B)*** *thumb.*

Thus, the DAG system adds an intrinsic elastic characteristic which allows the hand to automatically adapt to the shape of the grasped object, making the device's usage extremely intuitive.

2.1.2 System functionalities

The direct EMG control was implemented to assure reliability and robustness through an advanced hardware design. The two non-invasive surface EMG sensors are placed within the socket in correspondence of the two main forearm muscles to properly detect the muscles activity of the residual limb. These allow the patient to control the opening and closing of the device: a contraction of the flexor muscle sends the command to close the hand, whilst a contraction of the extensor muscle sends the opening command to the device. The two sEMG interact with *Hannes* through a dedicated control electronics module: the "EMG processing board" (Figure 40). This latter was custom-designed and sends the control signal to the "motor control board" module embedded in the *Hannes* hand via Contoller Area Network (CAN) protocol. The "motor control board" elaborates the commands and generates the Pulse-Width Modulation (PWM) signal to control the DC motor.

The prosthetic system is powered by a custom-made battery pack placed within the socket, designed to last up to one day thanks to the 2S1P Lithium polymer (LiPo) cells' configuration providing a 2000mAh capacity at a nominal voltage of 12V. The entire system is hence rechargeable with the provided battery charger (BCH) which is properly connected to its AC/DC Medical Adapter and its magnetic plug connector (Figure 45).

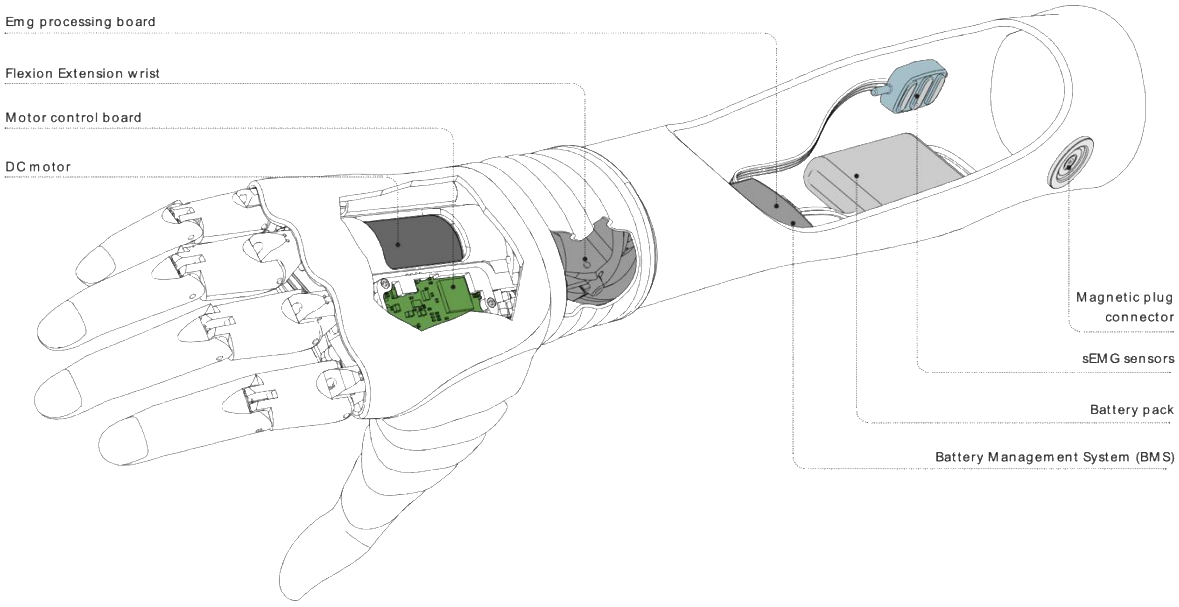


***Figure 40**: An overview of the entire prosthetic system.*

The control law that guides the entire prosthetics system is a two-nested PID (the outer loop regulates the motor current whilst the inner loop controls the velocity). The control is hence proportional, based on velocity references sent to the hand, that increase or decrease according to the muscles activity. The control parameters (gains and thresholds of the two EMG signals' amplitude) of *Hannes* are tuned for each user by means of a dedicated software Graphical User Interface (GUI) in order to exert the desired speed and force grasp performance.

Different grasp types are provided by a passive thumb rotation which is implemented through a custom-made spring-based plunger mechanism. This system can lock the thumb in three equally spaced positions (Figure 41), changeable with mechanical switches.

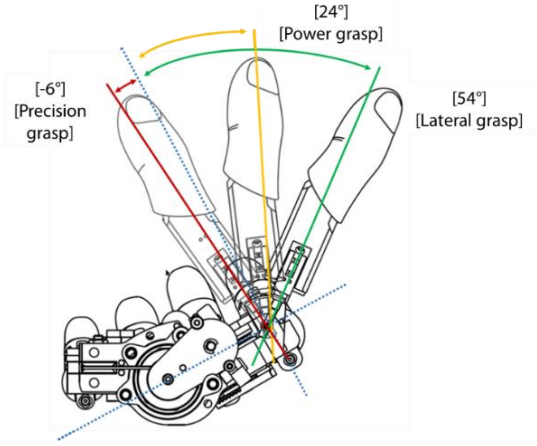


***Figure 41:** The three thumb configurations: (left) internal position, (middle) middle position, (right) lateral position.*

The three passive positions realise three different grasps (shown in Figure 42):

A. **Lateral grasp**: the thumb is in the most external location, its fingertip presses on the lateral surface of the index in the interphalangeal zone.

B. **Power grasp**: the thumb is in the intermediate location, allowing the grasp of objects with big dimensions and diameters. This grip is also known as palmar grasp.

C. **Pinch grasp**: the thumb is in the most internal position, in opposition with the tips of index and medium. The grasp is fine and precise, making possible to handle and hold an object of small calibre.

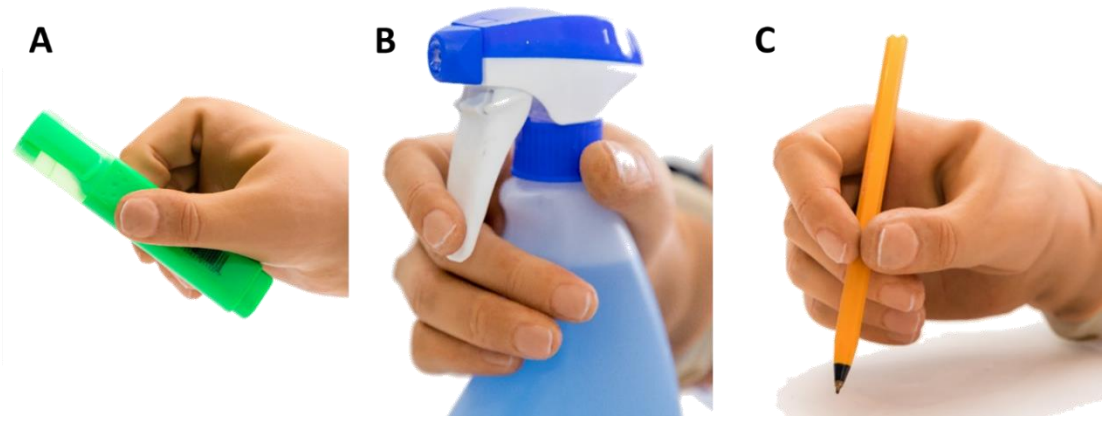


***Figure 42**: All the grasp types performed by Hannes: **A)** lateral, **B)** power and **C)** pinch grasp.*

The passive Flexion/Extension wrist joint uses a mechanical compression spring engaged by a cable-based system to emulate elasticity. The wrist extends and flexes around a pin-based revolute joint (Figure 43 A). When the wrist flexes, the flexion wire and a compression spring placed at the other end go in tension, compressing the elastic component and inducing slack to the extension wire. The opposite happens when the wrist extends. In addition, a passive Pronation/Supination module is added.

The wrist hence provides the user the possibility to perform:

- **Passive flexion and extension**. A locking mechanism permits to lock the wrist in five equally spaced different positions (one neutral, two for flexion and two for extension, as partially shown in Figure 43 B), otherwise it can be maintained in a release mode through a mechanical button. In this case the module naturally conforms itself based on interaction forces, enhancing the adaptability.

- **Passive pronation and supination**. The wrist module offers innumerable discrete positions in pronation and supination with a 360° mechanical and electrical slip ring connection. Once the mechanism is engaged, a series of steel spheres guided by two opened rings permit the hand to relatively rotate with respect to the socket. Along the rotation axis a four electrical contacts slip rings is custom-designed to connect the hand to the socket providing the power supply and, at the same time, making the control signal run through the CAN bus. This particular design, also called "quick release system", allows a rapid detachment under high traction forces and an immediate system shutdown in case of emergency.

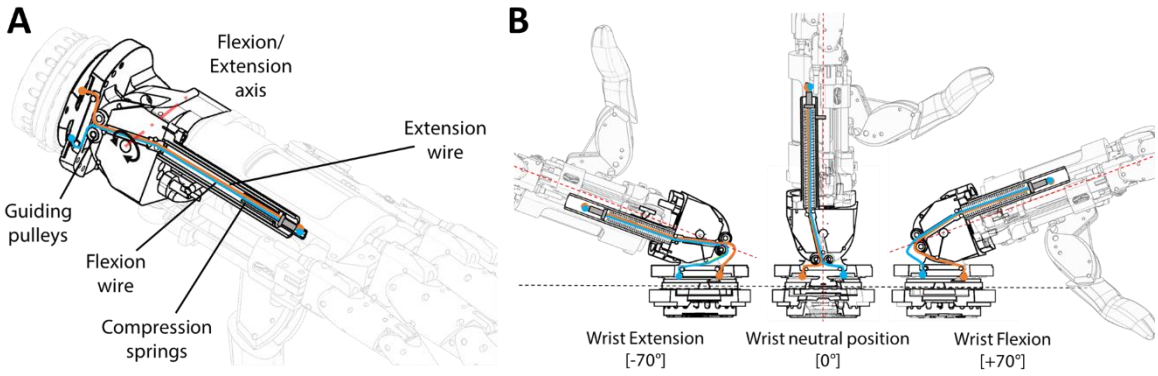


Figure 43: *FE passive wrist -* ***A)*** *Detailed cross section of the F/E wrist,* ***B)*** *the F/E wrist in its three configurations: (left) maximum extension, (middle) neutral position, (right) maximum flexion.*

Force and velocity tests were conducted to evaluate *Hannes* performances in modulating the grasp through EMG control and force regulation. As shown in Figure 44 A, *Hannes* starts moving as soon as the EMG closure threshold is achieved. In the EMG plots, the red lines correspond to EMG sensor activity for the opening, while the blue lines indicate the EMG sensor activity for the closing. The red and blue dotted lines show the activation thresholds for the opening and closing. When the digits reached the dynamometer, the force started to increase. Figure 44 A (Left) shows that the grasping force can be slowly increase or decrease by the user through a proper regulation of the EMG activity. The second experiment, shown in Figure 44 A (Right), demonstrates that when rampant EMG activation is performed the prosthesis can rapidly close and reach the maximum force of about 150 N in less than 0.25 s. The angular velocities of the main joints during a full-speed closure are shown in Figure 44 B. The black lines correspond to the mean values, while the orange areas indicate the Standard Deviation (SD). It is shown that MCP joints reach a peak velocity of about 4 rad/s (229°/s), whilst the proximal IP (PIP) joints reach a peak velocity of about half this value. *Hannes* can hence perform a full closure in less than 1 s.

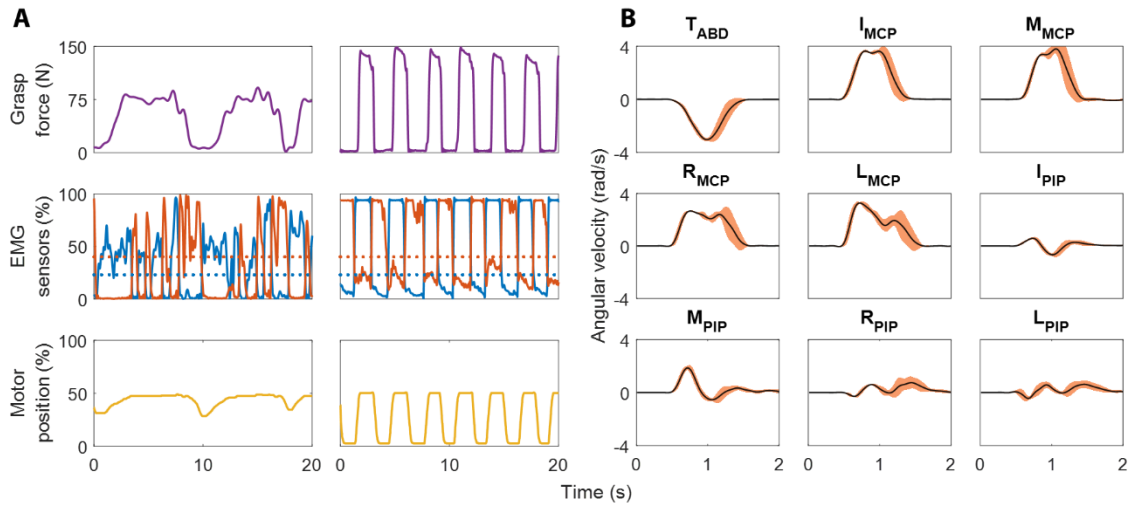


Figure 44: *Force and velocity tests:* ***A)*** *regulation of the force (left) and power grips (right) through direct EMG control,* ***B)*** *Angular velocities of the main articulations of Hannes during a closure performed with full speed.*

2.1.3 Clinical and technical features

Hannes is an externally powered myoelectric prosthetic device. The intended use is for mono or bilateral amputations from the transradial level.

From 2017, the *Hannes* hand is a CE marked medical device, classifiable, according to the UNI EN ISO 9999 norm, as a medical device of class 1. This certification allows the release to patients for domestic use.

Even if it is not yet purchasable, the CE mark makes *Hannes* for definition a commercially available product, equipped with a technical dossier and a user manual as well as all the needed accessories, shown in Figure 45. In particular, the battery pack, the magnetic ON/OFF plug, the two sEMG and the "Emg processing board" must be integrated on the amputee's socket by the orthopaedic technician. The AC/DC adapter and the Battery charger properly connected to the female Plug are instead provided to the patient in order to allow the recharge of the system.

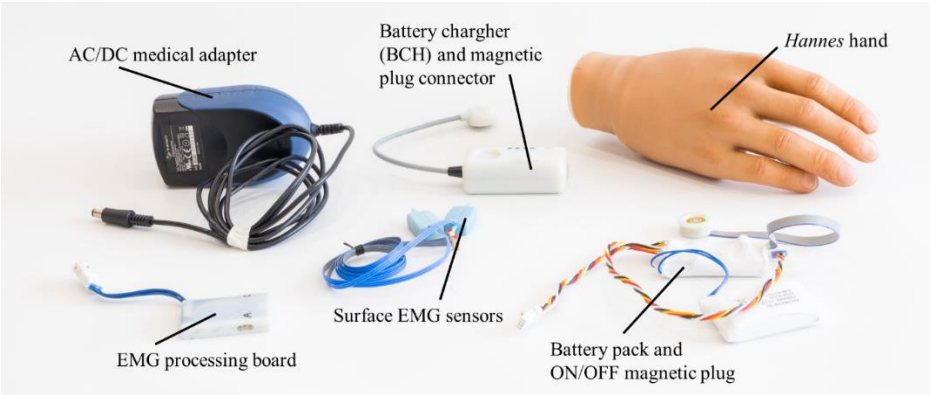


Figure 45*: Hannes prosthesis, covered with a skin-coloured glove, and all the related kit accessories.*

Hannes device introduces two different sizes for both left and right arm:

- $7\,3/4$, specifically designed for a 50th percentile of the European female population (or young people)
- $8\,1/4$, specifically designed for the 50th percentile of the European male population.

The thumb and the wrist are covered by a silicone bellow, while the whole hand can be covered with a silicone glove either transparent or more realistic skin-coloured.

The aim of the device is hence to substitute the missing limb, allowing the user to replicate the natural movements of the real hand and perform all the ADLs. It has been designed to execute the activities of the daily life and it cannot be used for particular actions, such as extreme sports with excessive load acting on the wrist and/or dynamic loads (downhill, mountain biking, push-ups...), the driving of heavy machines (construction machines), the operation of industrial machines and power tools.

Table 8 shows and summarizes clinical and technical features of *Hannes*.

Clinical features	
Available sizes	2
Multi-articulated hand	✓
Myoelectric control	✓
Wrist: Prono-supination	Passive
Wrist: Flexo-extension	Passive
Thumb Switch	✓
Adaptive grasp	✓
Prosthesis configuration with GUI	✓
Tipology of grasps	
Lateral pinch	✓
Lateral power grasp	✓
Power grasp in opposition	✓
Tridigital grasp	✓
Neutral position	✓
Hook	✓
Precision grasp	✓
Technical features	
Number of joints	10
Degrees of freedom	1
Number of actuators	1
Method of actuation	DC motor
Battery type	Lithium polymer
Environmental condition for the functioning	From -10° to 60° C, relative humidity: 80% without condensation
Opening	110 mm
Weigth of the single hand	480 gr
Maximum grip force	80 N
Maximum speed grasp	0,9 sec
Maximum load of the fingers with active operation (index and medium) with closed hand (i.e. when carrying a shopper)	150 N
Grip forces [N]	
Precision grasp	60
Power grasp	80
Lateral pinch	50

***Table 8**: Clinical and technical features of the Hannes system.*

Since *Hannes* is a medical device designed for transradial and transhumeral amputations, it is possible to associate two codes of the Italian National Classification of medical devices (CND), relating to the upper limb prosthesis with code Y0618 (EN ISO 0618):

- Y061809 TRANSRADIAL PROSTHESIS (FOR BELOW-ELBOW AMPUTATION)
- Y061815 TRANSHUMERAL PROSTHESIS (FOR UPPER-ELBOW AMPUTATION)

The device has passed tests on the electric safety, accordingly with the norm IEC 60601-1+AMD1 and IEC 60601-1-11, and tests on the electromagnetic compatibility, in accordance with the norm IEC 60601-1-11 and IEC 60601-1-2. Functional bench tests on every joint have been performed in order to validate the global mechatronic system and the single sub modules such as electronics, mechanics, software and control, and aesthetic and anthropomorphism.

A risk analysis has been written with the method: Failure Mode, Effects, and Analysis (FMEA). All identified dangers have been analysed, together with their potential sequence of events, and every possible risk has been estimated, using the norm EN 14971. The identified dangers are the following:

1. Electromagnetic energy: line voltage, leakage currents and singe fault.
2. Mechanical energy: parts in movement, incorrect ergonomics, uncontrolled device movements
3. Thermal/Sound energy: warming and noise from the parts in movement.
4. Inappropriate environment: reactions with substances which enter inside the device and emission/immunity.
5. Incompatibility with other devices or medicines.
6. Inappropriate instructions: maintenance and incorrect utilization procedure.
7. Incorrect use: unclear procedures and poorly comprehensible interface.
8. Output out of control: single fault or incorrect power supply.
9. Biological danger: contact reaction with the patient skin.

The associated damages have been indexed, and the severity of risks has been evaluated based on the related danger, on the duration and the type of exposure to which the user would be subject and to the eventual prognosis consequently a harmful event. Every residual risk was found to be acceptable, based on the device nature and intended use. The applied remedies decrease the probability that failures, included in every danger, take place. The adopted measures to reduce the probability of occurrence of a failure are the following:

- Usage of non-toxic materials, self-extinguishing and hypoallergenic (where needed).
- The device is designed to be easily used.
- The device is designed in order to impede the access to the mechanical parts and to the battery pack.
- The exposed components are rounded and not sharp.
- Rapid disconnection of the device through a rapid connection/disconnection system.
- Limitations in the electricity flowing in the motor driver e in the motor itself, thanks to limitations at the software level.

Furthermore, the protective measures listed below have been implemented:

- Overcurrent protection in the electronic Printed Circuit Board (PCB).
- Motor covered by a protective cover in order to not be accessible by the patient.
- Biocompatible materials.
- Training of the operator.

The additional safety information have been added wherever possible or necessary:

- Warnings on the user manual.
- Indications and contraindications on the user manual.
- Technical details on the user manual.
- Procedures and periodicity of the maintenance.
- Device symbols and data.

Moreover, the detected failures do not involve risks with a high severity level, since *Hannes* is not a lifesaver device, but belongs to medical devices of class 1. Due to the strategies carried out to lower risks, the device does not have collateral effects; moreover, the equivalent clinical products never documented collateral effects (research on MAUDE).

Regarding the prosthetic hand *Hannes*, a pre-market clinical trial (1.5: Pre-market clinical evaluation with *Hannes*) with three patients has been accomplished to verify technical functionalities, the safety and the reliability of the device. From the conducted study, it has been revealed that the prosthesis *Hannes* has proved to be safe for the subjects involved, both during the training period and the domestic use. Participants have particularly appreciated the peculiar characteristic of the poly-articulated *Hannes* hand: the flexible adaptable grasp, which makes natural every kind of grasp and fluid any kind of movement.

In conclusion, *Hannes* hand has proved to satisfy the conformity and the essential applicable requirements of the directive 93/42/CEE.

2.2 Pre-validation of the post-market clinical trial

The post-market clinical trial on which this pre-validation is based on has been formally accepted in September 2020 by the Ethics Committee of Emilia Romagna Region. The clinical trial is defined as "post-market" because *Hannes* is a CE marked medical device listed in the Italian Medical Devices Database, and this is enough to consider it "on the market", even if it is not yet purchasable.

Several documents have been compiled in the period between March and June 2020 during the scholar internship at Istituto Italiano di Tecnologia and revised by the Ethics Committee. The list of these attachments is reported hereafter:

- *Information Sheet to the Patient*
- *Informed Consent Module*
- *Flow Chart*
- *Centre-specific Forms:*
    - *Spirit Checklist*
    - *Local Evaluation of the Study*
- *Dataset OMS*
- *Main Investigator CV*
- *IIT-INAIL Agreement*
- *Insurance Preventive*
- *Technical Documentation:*
    - *CE mark*
    - *User Manual*
    - *Technical Dossier*
- *Conflict of Interest*
- *Investigator Brochure*
- *Information Letter to the General Doctor*
- *Synopsis*
- *Consent to the processing of personal and particular data*
- *Data Collection Form*
- *Clinical Protocol and its attachments:*
    - *Attachment A: NASA-TLX Questionnaire*
    - *Attachment B: SUS Questionnaire*
    - *Attachment C: TAPES Questionnaire*
    - *Attachment D: UX Ad Hoc Questionnaire*
    - *Attachment E: RHI-RoboHi Questionnaire*
    - *Attachment F: MMDT Instructions*
    - *Attachment G: SHAP Instructions*
    - *Attachment J: BBT Instructions*
    - *Attachment K: OPUS-UEFS Questionnaire*
    - *Attachment L: QuickDASH Questionnaire*

The pre-validation, subject of the thesis' first section, has been performed to verify the feasibility of the real clinical protocol and to get an idea of the achievable results. The pre-validation did not satisfy all the requests of the official clinical protocol. It was indeed conducted on a very small sample size, involving only 3 patients who already had experience with *Hannes*, with which a true statistical analysis was not possible. Furthermore, a simplified clinical protocol was performed, without the exploring study of Robotic Hand Illusion (because the experimental set up and the protocol were still under development) and with shorter times.

2.2.1 Clinical Protocol

The title of the official clinical trial is "*Studio per la valutazione dell'esperienza utente e dell'embodiment con follow-up a 3 mesi di pazienti amputati transradiali utilizzatori della protesi di mano Hannes*".

The pre-validation, as already explained, used a simplified version of the official clinical protocol. The pre-validation had multiple objectives, distinguished based on the level of importance, as in the official clinical research.

Primary Objectives

- Improvement over time (through the domestic use) and evaluation of the User Experience, based on the appreciation level of the device *Hannes*, its functionalities in the ADLs, technology acceptance, aesthetic aspect and comfort [42], [43], [28].
- Improvement over time (through the domestic use) and evaluation of the level of Embodiment of the device *Hannes*.

Initially, the evaluation was also conducted on the commonly used prosthetic myoelectric hand and then on *Hannes*, with periodic intervals in the three months following the handing of the prosthesis. This procedure allows both to compare *Hannes* with the commonly worn prosthesis and to evaluate the potential temporal influence on the user experience and the mechanisms of the embodiment.

Secondary Objective

- Evaluation of the efficacy of the device in terms of functionality, dexterity and the accomplishment of the ADLs.

Again, as for the primary objectives, the evaluation was conducted also on the commonly used prosthesis to permit a comparison with respect to the *Hannes* system.

2.2.1.1 Study Design

The pre-validation was carried out at Istituto Italiano di Tecnologia (GE). The participants were available, for a three-month period, to come to the centre in the pre-established dates to perform the baseline evaluation and the 3 follows up.

The study included the following activities, presented in chronological order and graphically summarized in the timeline of Figure 46:

- Baseline of the subject (**TB**), regarding the embodiment, functionality and user experience through tests and questionnaires with the commonly used prosthesis.
- Administration of functional and embodiment tests with *Hannes* (**T1**), carried out right after the baseline.
- Handing of *Hannes* hand to the patient for the three months period of domestic use (**T1**).
- Evaluation of the outcomes of the subject with *Hannes* through tests and questionnaires regarding the embodiment, functionality and user experience 1, 2, 3 months after the handing of *Hannes*. (**T2, T3, T4**).

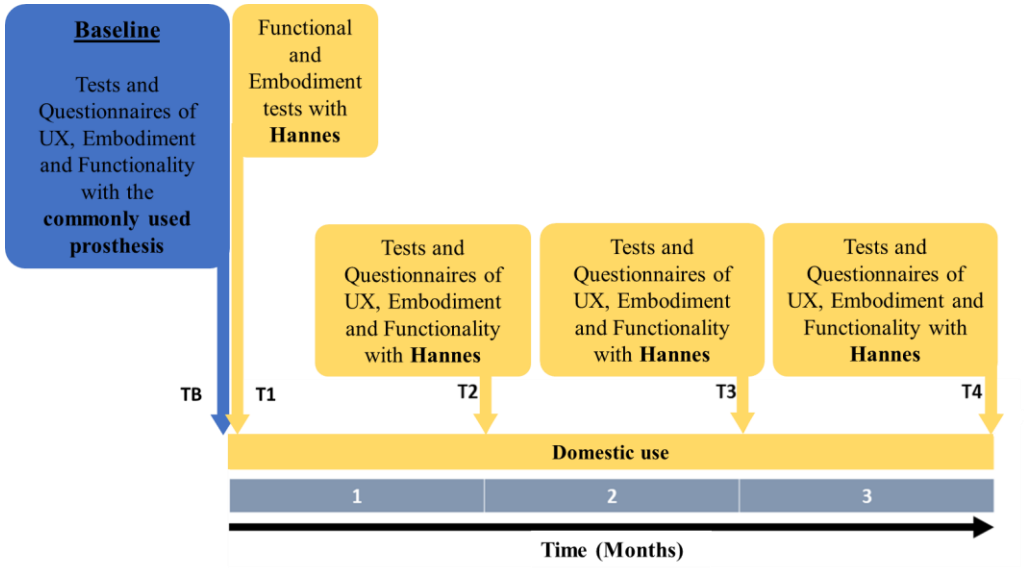


***Figure 46**: Timeline of the Clinical Trial Protocol.*

Three transradial amputees were recruited to conduct the simplified clinical protocol. The participants were myoelectric prostheses' experts but they were not new to *Hannes* hand, as requested in the official clinical trial. They indeed had some brief experience with this prosthetic hand in the past during the device development. In the Table 9 some fundamental participants' information are reported.

	Subject #1	Subject #2	Subject #3
Age	31	33	66
Age at amputation	26	23	14
Gender	Male	Male	Male
Missing hand	Right	Right	Right
Level of amputation	Proximal	Medial	Medial
Dominant hand	Right	Right	Right
Years of prosthesis use	4	10	52
Years of myoelectric prosthesis use	3	9	52
Commonly used prosthesis	Bebionic	Variplus	Michelagelo

Table 9: *Participants' information.*

The reason which brought to the recruitment of *Hannes* acquaintances was made to reduce the total time required by the setting up of the system and training, that should have been mandatory for novel *Hannes* users.

2.2.1.2 Methods

The methodology of this study comprised different instruments and procedures to evaluate and analyse different aspects of a prosthesis. An overview representing the entire tests and questionnaires methodology is shown in Figure 47.

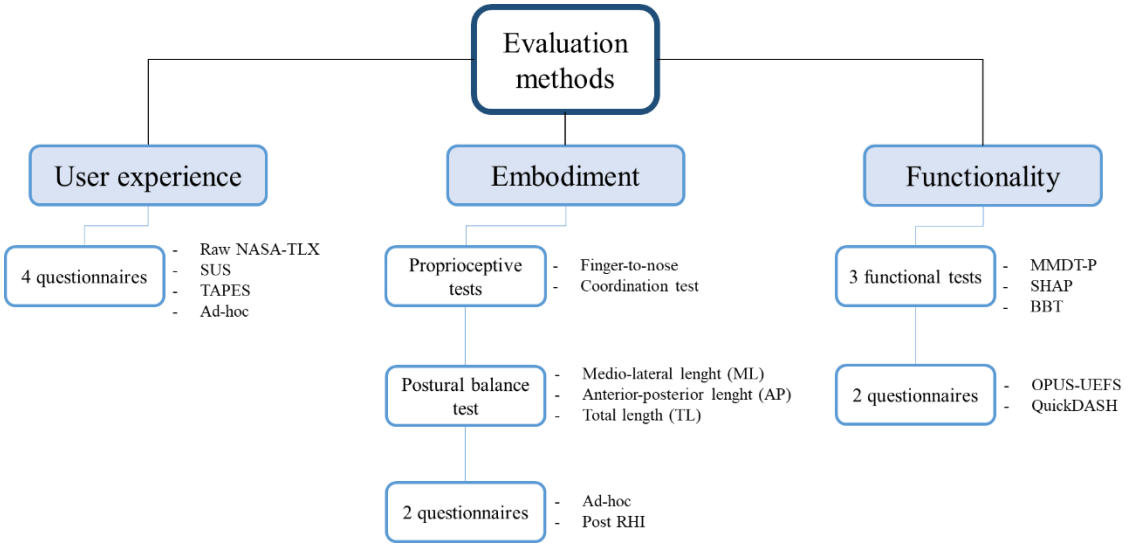


Figure 47: *Methods overview of the pre-validation.*

2.2.1.2.1 User experience

The investigation and evaluation of the potential variation in the participants' UX was conducted through four questionnaires. The initial three are internationally validated whilst the last one was designed ad hoc for this research:

1. The *NASA Task Load Index* (NASA-TLX) subjective questionnaire [44], initially designed for NASA astronauts, regards the workload perceived to assess a task or a series of performances. For this reason, this questionnaire must be filled right after the functional tests. The perception of the workload can, indeed, change, depending on the level of UX reached. It consists of 6 subjective subscales. Each of them possesses a description that the subject must read before rating. All these subscales are rated within a 20-point range with 1-point steps. They investigate:
    - The mental demand
    - The physical demand
    - The temporal demand
    - The performance
    - The effort
    - The level of frustration

    The scorings are converted into centesimal points being multiplied by 100 and then divided by 20:

    $$Score_i\ (\%) = \frac{score_i\ x\ 100}{20} \qquad (1)$$

    where *i=1,2,3,4,5,6* are all the items and $score_i$ is the score of each item.

    The 6 ratings are then combined to result in a single average index in hundredths:

    $$NASA - TLX\ score\ (\%) = \frac{\sum_{i=1}^{6} Score_i\ (\%)}{6} \qquad (2)$$

    where *i=1,2,3,4,5,6* are all the items.

    Low scores mean better and easier performances during the requested tasks. The real NASA-TLX method presents a second part, in which the user should choose which measurement is more relevant to workload, in his opinion. For this study, it was decided to adopt the raw NASA-TLX for time constraints. Although it lacks the individual weighting of the subscales, there is evidence supporting this shortened version, which could even increase experimental validity [45].

2. The *System Usability Scale* (SUS) questionnaire [46] provides a reliable validated tool for measuring the usability of a system. It comprises 10 items with five response

options, from “Strongly disagree” (1 point) to “Strongly agree” (5 points). It is a very easy scale and it can be used on small sample sizes assuring anyway reliable results. It indeed can effectively differentiate usable and unusable systems. The score of each odd question is decreased by 1 unit, while the even ratings are subtracted from 5. Then, the resulting scores are added together and multiplied by 2,5 to obtain a score between 0 to 100, differently from the starting score between 0 to 40. In formula:

$$SUS\ score\ (\%) = (\sum_{i=1}^{9}(item_i - 1) + \sum_{j=2}^{10}(5 - item_j)) * 2{,}5 \qquad (3)$$

where *i=1,3,5,7,9* and *j=2,4,6,8,10* and $item_i$ is the score of the item *i*, whilst $item_j$ is the score of the item *j*.

Based on research, a SUS score above 68 is considered above average, meaning that the system is usable. Hence, higher scores indicate higher usability.

3. The *Trinity Amputation and Prosthesis Experience Scales* (TAPES) [21] is a questionnaire which investigates different aspects of adjustment, both physical and psychosocial. It measures the overall appreciation in using the prosthesis and its influence in the performance of ADLs. It consists of 3 subscales with a 5-point rating scale regarding, respectively, the psychosocial adjustment, the activity restriction and the prosthetic satisfaction. It also includes an exploration of residual and phantom limb pain, and other medical problems. The overall index is given by the sum of all ratings:

$$TAPES\ score = \sum_{i=1}^{24} score_i \qquad (4)$$

where *i=1 to 24 are* all the items and $score_i$ the score of each item *i*.

$$TAPES\ score\ [\%] = \frac{TAPES\ score}{120} * 100 \qquad (5)$$

where 120 is the maximum obtainable score.

Higher scores indicate greater levels of adjustment. This scale was also administered in the pilot clinical trial of Chapter 1.5: Pre-market clinical evaluation with *Hannes*.

4. An ad hoc questionnaire was drawn up for this study. The subject had to answer to 22 questions giving a score from 1 (Maximum disagreement) to 5 (Maximum

agreement) points. The questions explore the level of technology acceptance [47] and the level of experience in the prosthesis usage. Furthermore, there are 3 open-ended questions which allow the participant to express his feedbacks and his advices. The questionnaire does not provide a unique final index and the answers must be singularly compared.

This questionnaire also includes questions related to the evaluation of embodiment. For this reason, it is cited again in the list of questionnaires below regarding the embodiment.

2.2.1.2.2 Embodiment

The level of embodiment was evaluated through tests, which should be able to assure an objective measurement, and questionnaires, including the ad hoc questionnaire mentioned above. The performed tests were the following:

- Proprioceptive tasks on the capability of the subject to be conscious of his whole body in the peripersonal space [48], [49]. If the tasks were performed correctly, this meant that the subject had a clear idea of his body and contemplated the prosthesis in it, giving evidence of an embodiment process.

    - The finger- to-nose test [50] required the subject to touch the tip of the nose with closed eyes. Starting with the arms laterally extended along the coronal plane and at the level of the shoulders, the patient had to place the tip of his index on the tip of his nose, first with the prosthesis and then with the sound-hand (Figure 48 A and B), maintaining the arm at the starting height. The evaluation was given by the measurement of the distance in centimetres (cm) between the two tips, which in the correct case should have been 0. If the deviation was distal/outwards, the value was marked with the sign "+", if it was proximal/inward, the value was marked with the sign "-".

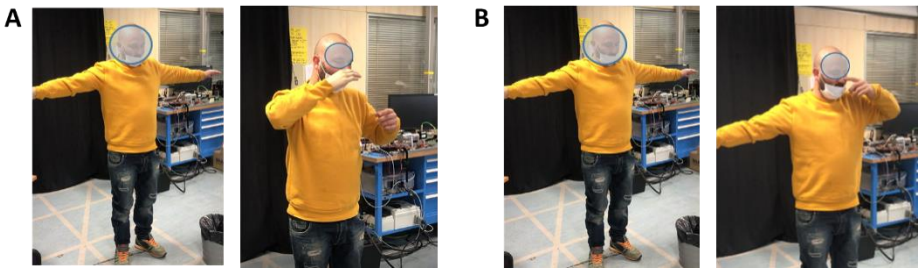


***Figure 48**: Finger-to-nose test – **A)** Prosthetic hand **B)** Controlateral hand.*

- Coordination tests of the upper limb [51] based on coordination tasks which implicate the two limbs together, were carried out. First, the subject had to extend his arms ahead in parallel to the median plane, maintaining them at the level of the shoulders. He was invited to place the tip of his prosthesis' index on the elbow, wrist and tip of index of the sound-arm, and then repeat the same actions with the contralateral arm in the prosthetic side (Figure 49 A and B). Again, the deviations from the targets were measured in cm. If they were distal/outwards, the values were marked with the sign "+", on the other hand, if they were proximal/inward, the values were marked with the sign "-". Subsequently, the patient had to join his hands with extended arms parallel to the sagittal plane below, at the level and above the shoulders (Figure 49 C). In this case, values marked with the sign "+" meant that one of the two hands was forward or upward with respect to the other one, while values preceded by the sign "-" meant the opposite (backward or downward).

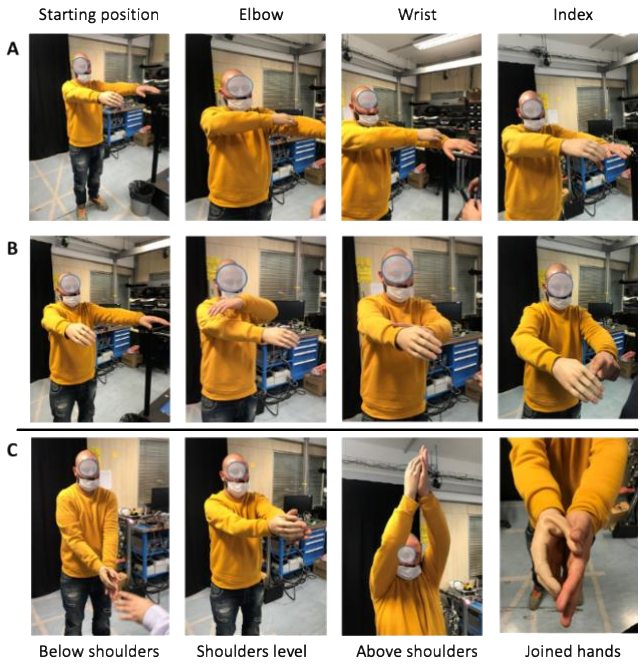


***Figure 49**: Coordination tests of the upper limb - **A)** with the prosthetic arm **B)** with the contralateral arm, and **C)** with both arms.*

- The postural balance test [32] required the subject to be motionless standing on a force plate, with his knees straight and arms down at his sides (Figure 50). First, the participant had to look at an eye-level fixation point on the wall for 60 seconds (eyes-opened – EO - condition). Immediately afterward, he had to close his eyes and remained standing for 60 seconds (eyes-closed – EC - condition). This test was

conducted in TB without any prosthesis and with the commonly used prosthesis. In T1, T2, T3 and T4 the test was performed only with *Hannes*.

The sample frequency of the data acquisition, made with the force plate (AMTI), was 1000 Hz, while the data were extracted and elaborated by a custom-made Matlab software [52] and filtered with a low-pass filter with a cut-off frequency of 20 Hz. The required parameters were calculated and generated in an Excel file as described in [52]. The programmed outputs were:

- Centre of Pressure (CoP) medio-lateral path length (ML), calculated as the cumulative displacement in the medio-lateral direction of the CoP [53], [54];
- Centre of Pressure (CoP) anterior-posterior path length (AP), calculated as the cumulative displacement in the anterior-posterior direction of the CoP [53], [54];
- Centre of Pressure (CoP) total path length (TP), calculated as the cumulative displacement of the CoP [53], [54];

The aim was to evaluate potential variations in the sway of the body with *Hannes*, during the 3-month follow-up, with respect to the commonly used prosthesis and to the absence of any prosthesis. It has indeed been demonstrated that, with an embodied prosthesis often worn, the sway decreases when wearing the prosthesis [32].

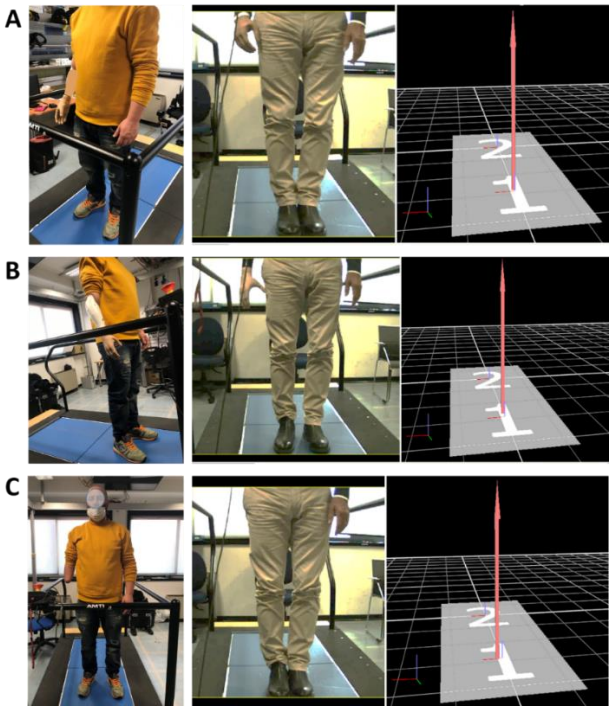
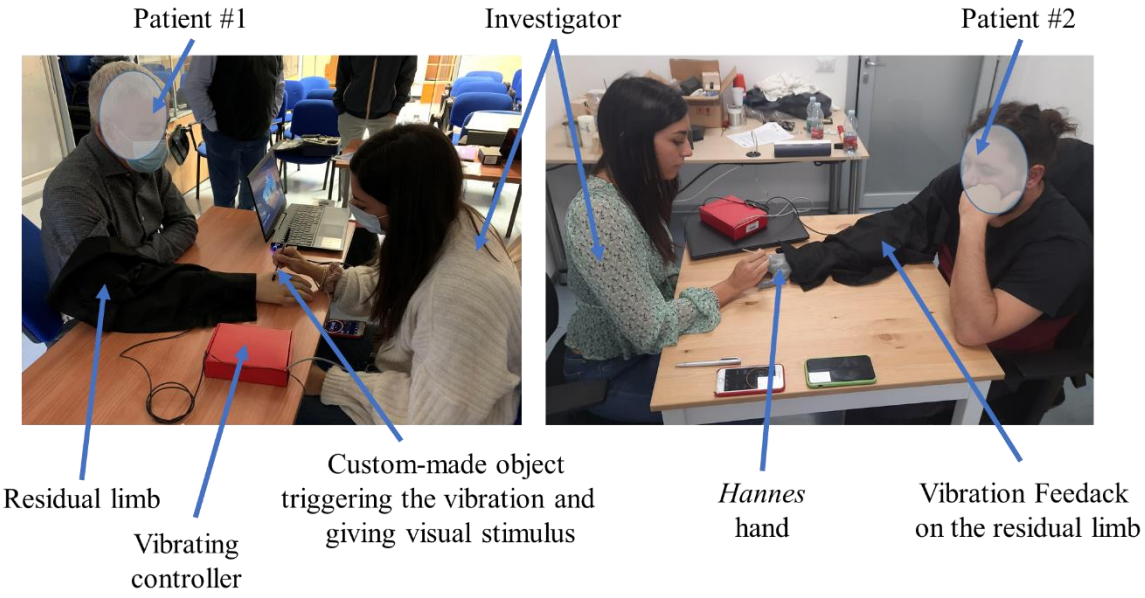


Figure 50: *The postural balance test – **A)** Usual prosthesis, **B)** Hannes hand and **C)** no prosthesis.*

The questionnaires specifically designed for the Embodiment evaluation were:

- The ad hoc questionnaire already described above in the list of questionnaires for the UX.
- Another ad hoc questionnaire administered after a session of a modified RHI, in which vibrotactile stimulation of the stump were triggered by the contact between

the detached bionic hand and a custom-made object managed by the investigator (



- Figure *51*).

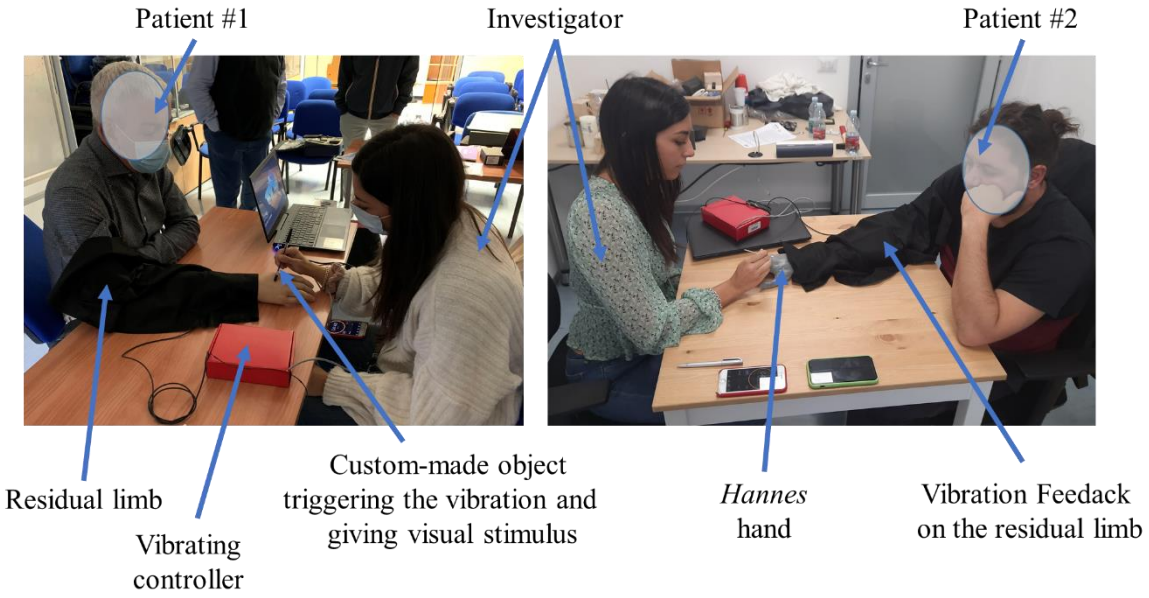


Figure 51: *Modified Rubber Hand Illusion (RHI) with vibrotactile stimulation.*

The paradigm of the RHI attempts to stimulate/induce and enforce the embodiment of the prosthesis by giving synchronous matched stimuli, visual and vibrotactile, to the detached prosthesis and the stump.

As for the "Ad hoc questionnaire" a unique final index is not provided and the answers must be singularly compared.

2.2.1.2.3 Functionality

For the achievement of the secondary objective, regarding the functionalities and dexterity provided by the prosthetic hand, functional globally validated tests were performed and standard questionnaires for the functional evaluation were administered. The functional tests chosen to be executed by the amputees with their prostheses were:

- The *Minnesota Manual Dexterity Test (MMDT)* [17], the internationally validated test already cited in the pilot clinical trial of Chapter 1.5: Pre-market clinical evaluation with *Hannes*. This test evaluates the dexterity obtained with the prosthesis by measuring the time spent to reorder a set of 60 small plastic discs. It must be specified that, because of prono/supination difficulties depending on the prosthesis design configuration, only the Placing task was administered (MMDT-P). In this task the objects must be placed, starting from the corner corresponding to the amputated side (in order not to invade and obstacle the field of view of the participant), one column after another in a board below, from the top to the bottom. The score is the time required to complete the task.

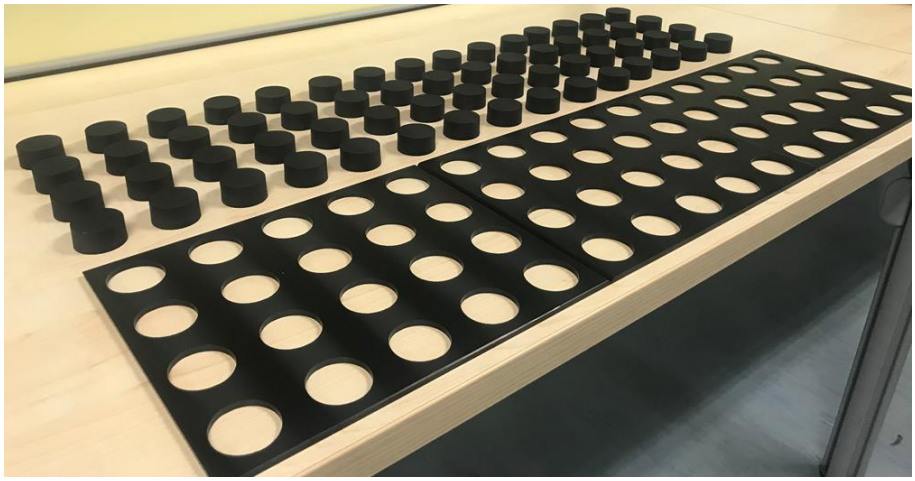


Figure 52: *Minnesota test.*

- The *Southampton Hand Assessment Procedure (SHAP)* [18], the clinical hand function test developed to measure the functionality of the upper limb. It was also applied to myoelectric prostheses [55] and already introduced in the pilot clinical trial of Chapter 1.5: Pre-market clinical evaluation with *Hannes*. The SHAP evaluates the ability of the subject in executing 6 different grips with 6 abstract objects:
    1. Spherical
    2. Tridigital
    3. Force

4. Lateral
5. Pinch with extended fingers
6. Pinch with flexed fingers

The grasps are executed twice, both with heavy and light objects.

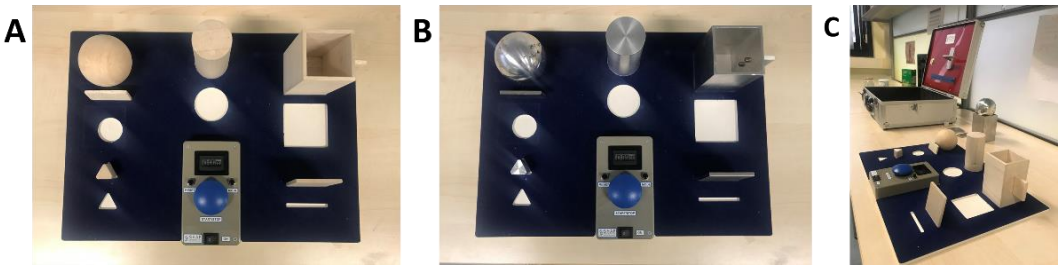


Figure 53: *SHAP abstract objects – **A)** light objects **B)** heavy objects **C)** overall setup.*

The second part involves the performing of 14 ADLs:

1. Pick up coins
2. Button board
3. Simulated food cutting
4. Page turning
5. Jar lid
6. Glass jug pouring
7. Cartoon pouring
8. Lifting a heavy object
9. Lifting a light object
10. Lifting a tray
11. Rotate key
12. Open/close zip
13. Rotate a screw
14. Door handle

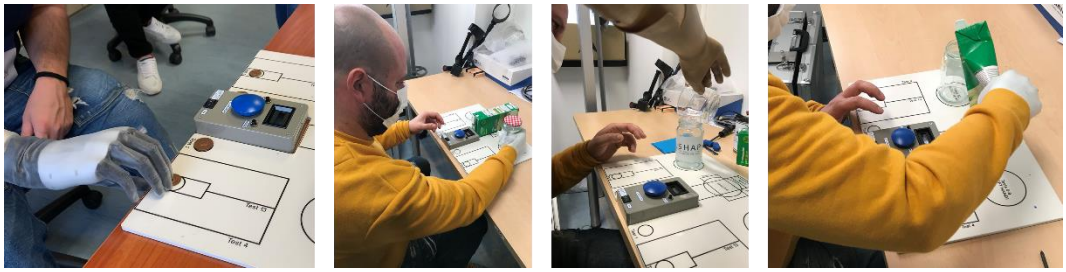


Figure 54: *Some of the SHAP ADLs.*

Each task of the SHAP test is timed by the subject himself, who must perform the test while seating. Using the method described by Light, Chappell and Kyberd, which is implemented in the SHAP software on the SHAP website, times can be normalised to 100 and each of the 26 tasks is classified within one of the 6 prehensile patterns. This online process generates the SHAP Functionality Profile, giving a quantifiable assessment of hand function that can be broken down into the six prehensile patterns. In this way, it can be visualised whether a participant has exceptional power and spherical grip, or impaired function in the ability to perform finer manipulations such as tip and tripod grips. Finally, an Index of Functionality

(IoF) can be generated always on the SHAP website. This index provides an overall assessment of hand function. The scores between 95 and 100 are considered referable to the normality range.

- The *Box and Block Test (BBT)* [56], [57], which measures unilateral gross manual dexterity. It is composed by a wooden box divided into 2 compartments separated by a wall, and by 150 wooden cubes with a lateral length of 2.5 cm. The subject must move, one by one, the maximum number of cubes from one compartment to the other one, without touching the wall, within 60 seconds. The tool must be placed at the participant midline, so he must be seated, and the compartment with the cubes must be in the prosthetic side. Additionally, a 15-second trial period is permitted before starting the evaluated trial. The score is based on the number of individually transferred cubes from one compartment to the opposite one.

Figure 55: *Box and blocks test.*

The standard questionnaires for the functional evaluation, mainly exploring the capability of performing daily life tasks, were:

- The *Orthotics and Prosthetics User Survey Upper Extremity Functional Status (OPUS-UEFS)* [19] scale, which is the only one able to measure in a specific way the functional activities executed by prosthesis' users. It is a self-administered questionnaire which includes 28 activities concerning the self-care and the usage of daily life instruments. The evaluation method consists in a 5-point scale from 4 (the subject is able to easily perform the task) to 0 (the subject is not able to perform the task), besides the "not applicable" choice, with the additional information about the performing of the task with or without the prosthesis. The number of tasks performed

with the prosthesis are counted (*n*). The total achievable score (formula 5) is given by this number multiplied by 4 (maximum score). The scores in which the prosthesis is involved are summed (formula 6) and the goodness (in percentage) (formula 7) of the items performed with the prosthesis is given by the total real score divided by the total achievable score and then multiplied by 100. In formula:

$$Total\ achievable\ score = 4 * n \tag{6}$$

where n is the number of tasks performed with the prosthesis.

$$Total\ real\ score = \sum_{i=1}^{n} I_{prosthesis_i} \tag{7}$$

where $I_{prosthesis}$ are the items performed with the prosthesis, n is the number of tasks performed with the prosthesis and *i* is the counter of all the items performed with the prosthesis.

$$Goodness\ [\%] = \frac{Total\ real\ score}{Total\ achievable\ score} * 100 \tag{8}$$

Finally, the percentage of the items performed with the prosthesis is calculated with respect to the total items:

$$Percentage\ of\ utilization\ [\%] = \frac{n}{28} * 100 \tag{9}$$

where 28 is the number of items included in the questionnaire.

- The *Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH*) [58], [59] is a shortened version of the DASH questionnaire used in the pilot clinical trial of Chapter 1.5: Pre-market clinical evaluation with *Hannes*. It provides a general measure of the functional activities and the musculoskeletal disorders of the upper limb, validated for amputated patients. The subject must evaluate his capacity in performing the 11 actions described thinking about his last week, by choosing from a 5-point scale where 1 is "No difficulty" and 5 is "I could not do it". There are also 2 optional modules of 4 statements each, regarding the working and sporting/recreational environment. The DASH score ranging from 0 (no disability) to 100 (most severe disability) is obtained with the following formula:

$$DASH\ score\ [\%] = \left[\frac{\sum_{i=1}^{n} score_i}{n} - 1\right] * 25 \tag{10}$$

where n is the number of completed question, i is the counter of each completed question and $score_i$ is the score of each completed question.

To calculate the DASH score at least the 90% of the questions must be completed. In this case, the lower the final score is the better the performances are.

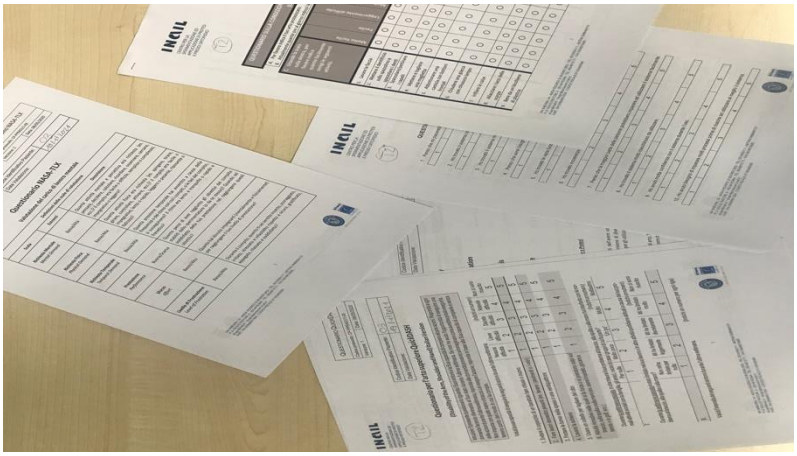


Figure 56: *Questionnaires.*

For what concerns the pre-validation carried out for this thesis with a so small sample size a statistical analysis was not possible. The analysis of the results, given by the tests as well as by the questionnaires, exploits the observation of trends over time within the single patient' results to evaluate an improvement or a deterioration over time. Furthermore, comparisons between the baseline (**TB**) and the last follow-up with *Hannes* (**T4**) can be examined to demonstrate if *Hannes* hand is better than the other commonly used prostheses, as predicted. The percentage of improvement or deterioration of *Hannes* with respect to the commonly used prosthesis (TB) is obtained with the following formula:

$$T4 - TB\ [\%] = \frac{(T4 - TB)}{TB} * 100 \qquad (11)$$

2.3 Embodiment stimulation – a pilot study

The feasibility pilot study on the embodiment stimulation, subject of the second section of this thesis, regards a wider exploring study carried out at Istituto Italiano di Tecnologia. The topic of this investigation is indeed the object of a bigger paper submitted to a special collection (Research Topic) of Frontiers in Neurorobotics, Frontiers in Psychology, and Frontiers in Human Neuroscience. The title of this collection is: "Exploring the Embodiment of a Virtual Hand in a Spatially Augmented Respiratory Biofeedback Setting". The feasibility study was performed on a smaller sample size with respect to the study of the paper to try the setup and to verify the research hypothesis.

As already described in Chapter 1.6: Embodiment, the embodiment can improve the control of artificial limbs [60], positively affecting the performance of several tasks. For this reason, the embodiment evaluation is currently under investigation and development [61] (as deeply discussed in Chapter 1.6.1: Embodiment evaluation) within the human-machine interface field [24]. The aim is to develop novel methods and approaches to improve the UX of prosthetic users and, at the same time, to decrease the prosthesis abandonment rate (as reported in the Chapter 1.6.2: Embodiment stimulation).

Many studies focus on visuo-tactile stimulation to enforce this process, as the modified paradigm of RHI exploited in the pre-validation of the first section (explained in the subchapter 2.2.1.2.2: Embodiment). Since the psychophysiological conditions and their control are involved in cognitive processes related with body awareness (as embodiment) it is possible to assume that they can affect the embodiment phenomenon.

It has been proved that the modulation of the Respiratory Rate (RR) influences human beings' mental and physical conditions (hence the psychophysiological state) [62]. Specifically, a controlled, deep and slow breathing (SB), typical of meditation techniques, can induce a calm psychophysiological state. It was indeed observed that the Heart Rate (HR) decreases when the RR is around 6 breath/minute, thanks to a synchronized event [63]. Hence, it could be supposed that a slow RR can lead the subject to a psychophysiological state in which the multisensory inputs are easier to incorporate, facilitating and stimulating the embodiment process.

Starting from this hypothesis, the proposed feasibility pilot study aimed to investigate the effects of a forced modulation of the psychophysiological state through a slow breathing in the process of body ownership. This to stimulate the embodiment of a virtual right hand

(*Hannes* hand) using a Spatially Augmented Reality setting and Respiratory Biofeedback (Spatially Augmented Respiratory Biofeedback – SARB).

In order to do that an interactive setup which allows the subject to control the opacity of a virtual hand (without moving it as in classical RHI and VHI) through the RR was designed. The focus was on the ownership aspect of the embodiment, considering the agency component (being able to move the virtual hand) as a future target.

The **final goal** of this entire exploring study was the realization of a "rehabilitative" tool for an embodiment stimulation and training, replicable at home by any amputee with a very basic setup. This tool was specifically designed thinking about *Hannes* users. In fact, the limb to be embodied is a virtual hand which replicates the real *Hannes* prosthesis. The idea is to intrinsically induce the embodiment process of the real prosthesis through the virtual training with the virtual hand, since they look identical.

2.3.1 Experimental background

Despite a totally immersive virtual reality has been showed to provide consistent results in VHI as obtained with RHI tests [64], for this exploring study a mixed reality approach was implemented, as the final goal was to elaborate an at home-usable tool with a very simple set up.

It was concluded that the Spatially Augmented Reality (SAR) settings [65], augmented realities based on projection, were able to provide the desired conditions. Within SAR environments immersive contents are produced by overlapping the real world and the virtuality [66]. Exploiting a reality-based interaction the continuity between the virtual hand and the subject's limb is provided, as a real prosthesis would do in real life or as the rubber hand in the RHI studies.

2.3.2 Study design

The study design introduced one independent variable, the Breathing Rate, with two conditions:

- Slow Breathing (SB)
- Normal Breathing (NB)

The breathing rates asked to be maintained in these two conditions were chosen based on literature. [67] defined any respiratory rate from 4 to 10 breaths/minute (0.07–0.16 Hz) as slow, and the ones from 10 to 20 breaths/minute (0.16–0.33 Hz) as typical for human beings (normal). Within the first range the rate of 6 breaths/minute was selected accordingly to the

review [68] as the target in the SB condition, whilst the rate of 14 breaths/minute was established as the target in the NB condition as in [69].

The pilot study had a within-group design. In fact, all subjects performed the task in all conditions (two). The two experimental conditions were investigated in different days, but never exceeding a maximum period of 14 days. The order of sessions was counterbalanced, as in a randomized repeated measures design.

The measured parameters were collected in-session, during the 16 experimental trials:

- The Respiratory Rate (RR) (evaluated accordingly to the acquired breaths), by means of the microphone integrated in the headphones and thanks to an already existing custom-made C# script.

Post session, the level of embodiment was evaluated through:

- The subjective questionnaire, composed by 15 items and exploring different aspects of the embodiment and of the experimental experience. Precisely, the emotional engagement, the perceived stress, the body ownership of the virtual hand, the disownership of the real hand, the interoceptive intensity and the sensation of the relationship between the virtual hand appearance and the respiratory rate. Furthermore, it was questioned an estimation of the 16 experimental trials' total time in order to evaluate the immersivity and the participants' subjective time perception.
- The proprioceptive drift, measured at the end of the experiment (after the neutral state video). The proprioceptive drift was identified as the lateral distance between the actual position of the phone during the experimental session (signed at the beginning while preparing the setup with a piece of tape) and the one estimated by the subject at the end of the experiment without watching. The drift towards the virtual hand is an implicit objective measure of the reached level of embodiment.

Participants

12 (4 females) adults (Age, mean ± SD: 26,91 ± 2,15 years) participated to the study. They were all volunteers from IIT.

In addition, 2 males of age, respectively, 66 and 33 years, right transradial amputees and *Hannes* users were subjected to the same experiment of the other participants, simulating the real home testing. In this case the smartphone was placed under the stump, the amputees were asked to think about their phantom hand and the subjective questionnaire was partially

adapted (some statements referred to the limb and not to the hand). This purely worked as a feasibility study to investigate the users' availability in using this tool as an "embodiment training".

Statistical analysis

The statistical analysis was conducted only on the 12 healthy subjects, since the number of amputees included in this study was too small.

The Breathing Rate dataset was evaluated via Student's t-test to check if the subjects were able to control their own RR and to maintain it to the target value (depending on the given condition). This dataset was also used to calculate the number of successful trials as a performance measure (the number of trials in which the subjects were able to make the virtual hand shake).

The questionnaire scores were analysed via Wilcoxon signed-rank test with condition (SB vs NB) as a factor. Session time estimations and proprioceptive drifts were analysed via repeated-measure ANOVAs with condition (SB vs NB) as a factor.

All analyses were performed using JASP[17] software package, and $p < 0.05$ was considered significant.

The task

In this SARB paradigm the task required the subjects to maintain a target respiratory rate slow or normal (SB or NB depending on the given condition) to minimize the transparency of the *Hannes* virtual hand (or, in other words, to increase its opacity). By materializing the virtual hand it was possible to "feel" the energy of a sliding sphere (once under the hand) and to trigger a simultaneous visuo-tactile event: a visual shaking of the virtual hand on the screen and a tactile vibration produced by the smartphone on the real hand of the subject. The aim of each trial was indeed the realization of this event before the disappearance of the sphere (the sphere was moving from a hole on the left to a hole on the right along an inclined surface).

[17] JASP - A Fresh Way to Do Statistics (jasp-stats.org)

2.3.3 Setup

The whole experimental setup (shown in Figure 57) was composed as described below:

- A laid-out monitor of 21'' 16:9 on a desk, slightly inclined towards the subject to allow an easier visualization of the screen.
- Black blankets over the subjects' arms and covering the monitor's profile, to let the subjects concentrate on the non-immersive virtual environment presented on the screen.
- Over-ear headphones with an integrated flexible microphone placed right in front of the mouth to detect the subject's breaths.
- A Smartphone (Samsung S7) for vibratory stimulation, placed under the subject's right hand.
- A laptop (Alienware M15: Windows 10 Home 64 bit), connected to the monitor by means of a HDMI cable, used to run the Unity software (which presents the SAR and permits the real-time processing of the breathing data).

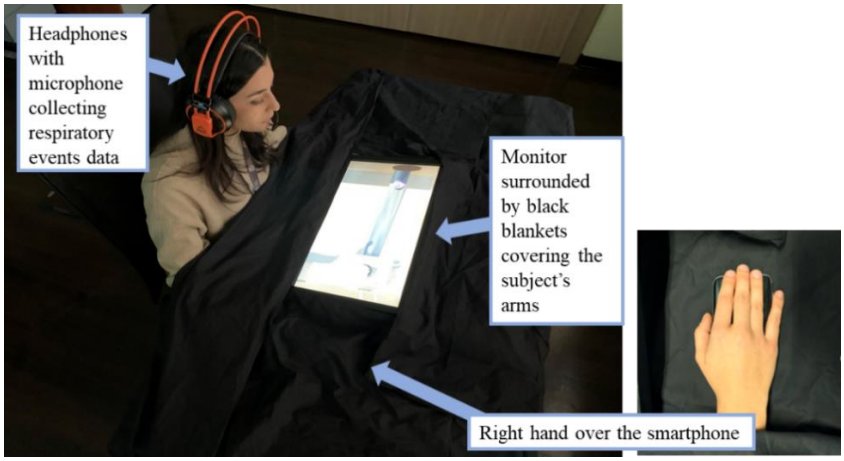


Figure 57: *Overview of the experimental setup.*

To increase the immersivity and reduce the surrounding disturbs the room light was dim during the entire experiment.

2.3.3.1 SAR environment

The SAR environment was developed in a Unity project, enriched by the respiratory biofeedback features (based on RR detected by the microphone of the headphones), generating the SARB setting.

The custom-made Unity project developed contained a total of 18 scenes. The first scene was unique, then the project provided two parallel options (based on the task condition chosen in the first scene). Finally, the last 5 scenes went back to being unique. Hence, both

conditions were constituted by a total of 13 scenes. The organization of the build settings is graphically represented in Figure 58.

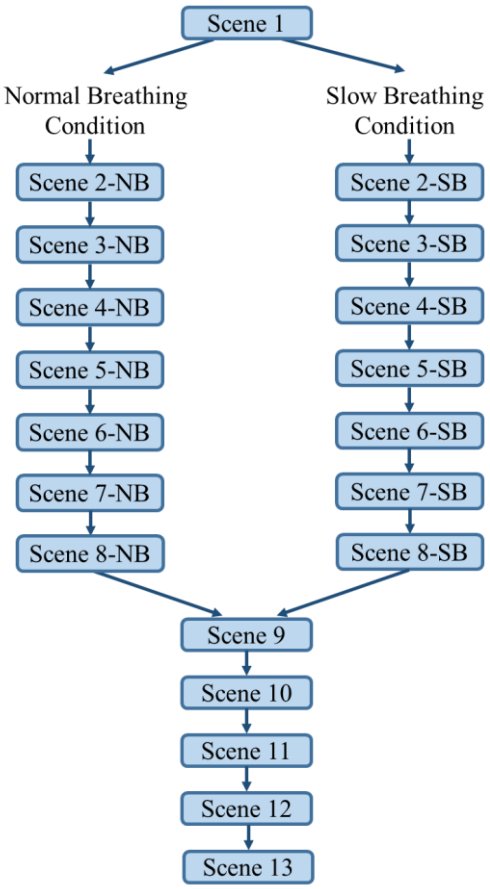


Figure 58: *Build Settings organization.*

In the first scene a panel was added in order to allow the inserting of the subject ID, the selecting of the condition (SB or NB) and the integration of the IP address (which allows the communication with other devices within the same local network). The same IP address was hence inserted in the Unity application on the smartphone (developed by an external group of research), allowing its connection to the Unity software running on the laptop.

The second scene was used for the acquisition of the subjects' personal information (Age, Gender, Weight, Height, Work or Study Activity collected for future works) through over-writable textboxes. The stress level of the experimental day and of the period was acquired through sliders with a 5-point rating scale.

A scene containing a 3-minute video of moving geometric patterns was introduced at the beginning (right after the subjects' personal data acquisition) and at the end of the experiment to induce a neutral mental state. This video was added to "isolate" the experiment session from the other external actions.

The main scene with the experimental task showed the inside of a cardboard box in which an energetic sphere slid on an inclined surface, from a hole in the left wall of the box towards another hole under the 3D model of the right hand *Hannes* (leant on a pierced support) (Figure 59).

Figure 59: *Main experimental task scene.*

The inside of the box was created firstly by connecting 3D objects (3 cubes and 1 plane) and then assigning to these latter a "cardboard box" material (downloaded from the Unity Asset Store). The inclined surface on which the sphere slid was a plane with an attached metallic material, in order to give the aspect of a slide.

The 3D model of *Hannes* was imported in Unity from an already existing Blender file, based on *Hannes* CAD. The hand was leant on a pierced rectangular support with a semi-transparent aspect to permit the view of the black hole under the hand. The script "Transparency.cs", written in C# language, was applied to the *Hannes* hand. This script was the responsible of the transparency changing, acting on the *Alpha* parameter of the 3D object *Hannes*. *Alpha* was set to 0,5 at the beginning of the trials (Figure 60 A). *Alpha* varied during the trials according to the maintenance of the correct Respiratory Rate (based on condition). The breaths were detected through the microphone, processed through a series of already existing custom-made scripts. For both conditions, when a new frequency of breath was detected it was compared with the target breathing rate (6 in SB and 14 in NB) to produce an *Alpha* value between 0 (fully transparent) and 1 (fully opaque). For the success of the task in each trial (the materialization of *Hannes* hand and the production of the visuo-tactile vibration) *Alpha* needed to be higher than 0,8 (Figure 60).

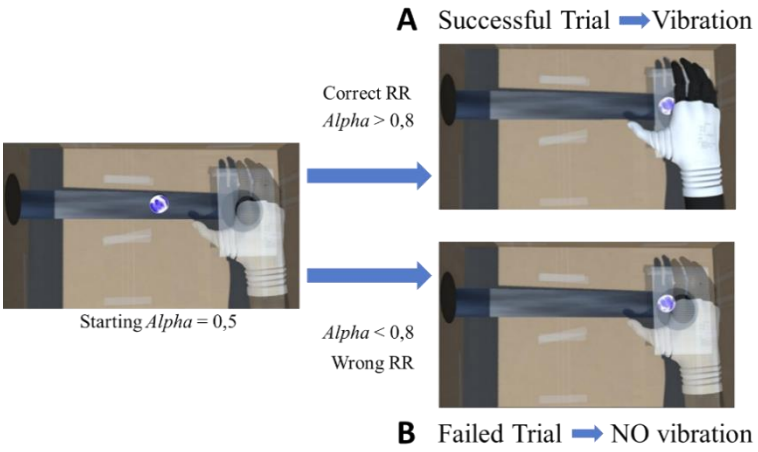


Figure 60: *Different virtual hand visualizations and consequences -* ***A)*** *Full solid aspect and* ***B)*** *Semi-transparent aspect.*

During preliminary tests the quick changes in the hand visibility often constituted a serious obstacle to the subjects' accomplishment of the task, especially when the sphere was approaching the hand. Therefore, a facilitation was introduced to increase the degree of success. In fact, in case of occasionally breathing rate far from the target the *Alpha* value was decreased only by 0,01 instead of being calculated again.

Always on *Hannes* hand the script "Shake.cs" was added as Unity component allowing the shaking of the virtual hand when *Alpha*>0,8. The visual shaking event was triggered when the sphere reached specific coordinates placed under the hand. The shaking time was set to 1 second.

Simultaneously to the visual shaking of the hand, the event of the "collision" between the sphere and the hand (when *Alpha* > 0,8) was converted into a message sent to the smartphone to generate the vibrating stimulus. To enable this haptic event, an Application Program Interface (API) was developed to trigger the smartphone vibration and to set up the wireless communication (based on a local network) between the laptop and the smartphone. This connection was based on a Unity (Windows) desktop app sending to a Java back-end (running on a Tomcat server) a request for a Unity (Android) mobile.

The "energetic sphere" was a 3D object on which a package called "Glowing orb" (downloaded from the Asset Store) was applied. This package was able to give the sphere a glowing and dynamic aspect, allowing to have a kind of "energetic effect". The sphere was designed as "energetic" to create a logic connection with the vibration, passively experienced by the inactive hand. The sphere was equipped with the script "Sphere.cs", which was linked to the other two scripts "Shaking.cs" and "Transparency.cs" (belonging to *Hannes*). In the

"Sphere.cs" script, the sliding of the sphere on the inclined plane was implemented with a uniformly accelerated motion. The sphere's variables "speed" and "acceleration" were respectively set to 0,01 and 0,0003 seconds to properly complete the sphere's path in 1 minute (from the black hole in the left wall of the cardboard box to the black hole under the hand). This timing was equivalent to the duration of 1 trial. The number of trials' repetitions was imposed based on the session (training and experimental). In the training trials this variable was equal to 2, while in the experimental trials it was equal to 16. Thus, the training session lasted 2 trials (hence 2 minutes) while the experimental session lasted 16 trials (hence 16 minutes). As soon as the sphere reached specific coordinates (located under *Hannes*) the script "Sphere.cs" called the script "Shaking.cs" if the *Alpha*>0,8 condition was respected. After reaching the final coordinates, and after 1 second, independently from *Alpha* and from the vibrating event, the sphere was programmed to return in its initial coordinates and hence to immediately start a new trial.

The "Rigid body" component was also added to each 3D object to make the objects solid and not penetrable. All the other boundary scenes contained panels with instructions. Only the 3 scenes which preceded the neutral state video contained the 14 items of the questionnaire. An over-writable textbox was also inserted to acquire the subjects' time estimation of the 16 experimental trials' total time. Each scene contained the script "New scene.cs", which allowed to pass to the next scene. Mostly, this script was applied to buttons. However, in the trials scenes it was attached to the sphere and automatically triggered from the end of the last trial.

The data generated by the Unity software during the experiment were collected in a TXT text file, named with the subjects' ID and automatically generated at the end of the last Unity scene with the click of the "FINISH" button. The TXT file contained the following features:

- The experimental condition: SB or NB.
- The subject ID.
- The subject personal information (e.g., age, gender...).
- The timestamp coinciding with the start of the Unity software
- The timestamp coinciding with the start of the first neutral state video.
- The timestamp coinciding with the start of the training session.
- The list of breathing events with their time stamps during the training trials.
- The number of repetitions of the training session.
- The timestamp coinciding with the start of the experimental session.

- The list of breathing events with their time stamps during the experimental trials.
- The estimation of the 16 experimental trials' total time.
- The timestamp coinciding with the start of the second neutral state video.

2.3.4 Experimental Procedure

The subjects were asked to sit in front of a desk, wear the headphones and place the arms at the sides of the monitor, in order to form a 90° angle with the elbows. The right hand was located on the smartphone, then it was adjusted in order to align as much as possible the subjects' real wrist to the one of the virtual hand in the monitor. The subjects then agreed to start the experimental session, allowing the experimenter to run the custom-made Unity software. Figure 61 summarizes and schematizes the entire experimental path, showing the main scenes and the order of succession. The experimenter read aloud each textbox appeared on the screen for the entire experiment, ensuring that the subjects understood what was about to happen before passing to the next Unity scene. The investigator waited for the participants' commands in order to click the different buttons accordingly.

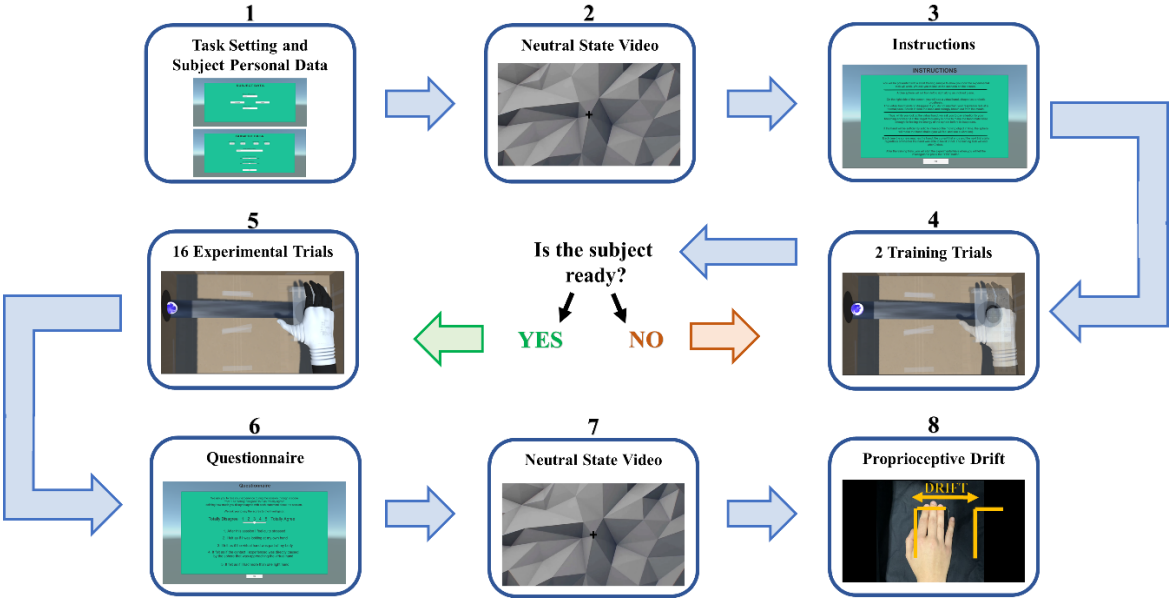


Figure 61: *Logic scheme of the experimental procedure.*

In the first scene (Figure 62 A), the experimenter inserted the subjects' number, the IP address to connect the smartphone and chose the experimental condition, SB or NB.

In the second scene (Figure 62 B) the investigator filled the subjects' personal data while reading aloud the different sections (Age, Gender, Weight, Height, Work or Study Activity collected for future works) in order to properly transcribe the subjects' answers. The subjects were also asked to indicate if it was a stressful period and a stressful day with a score on a 5-point likert-type scale where 1 was "Total Disagreement" and 5 was "Total Agreement".

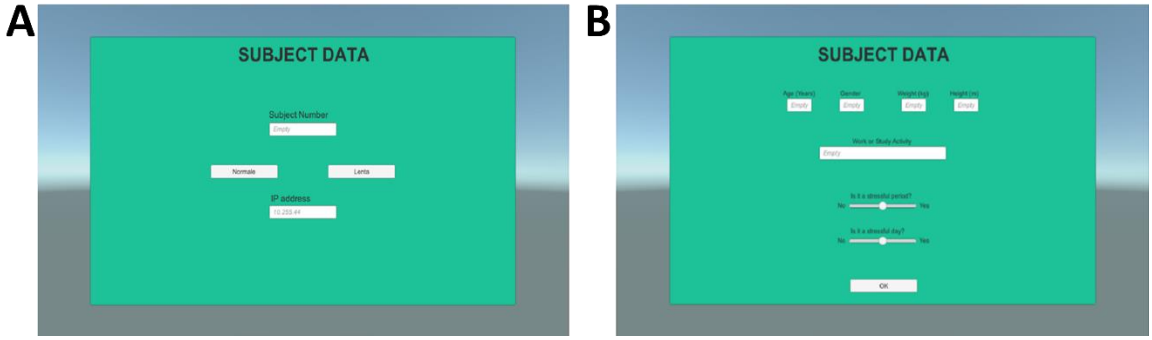


Figure 62: *First two scenes -* ***A)*** *Task Setting and* ***B)*** *Subject Personal Data.*

After completing the personal data acquisition, the experimenter moved to the first instructions scene by clicking the "OK" button (Figure 63 A). In the same way he moved to the first neutral state video (Figure 63 B). This latter had the goal to induce a neutral mental state before the assignment of the task. The investigator asked the subjects to stay still while fixing the cross in the middle of the screen and to warn him when the "OK" button appeared instead of the cross.

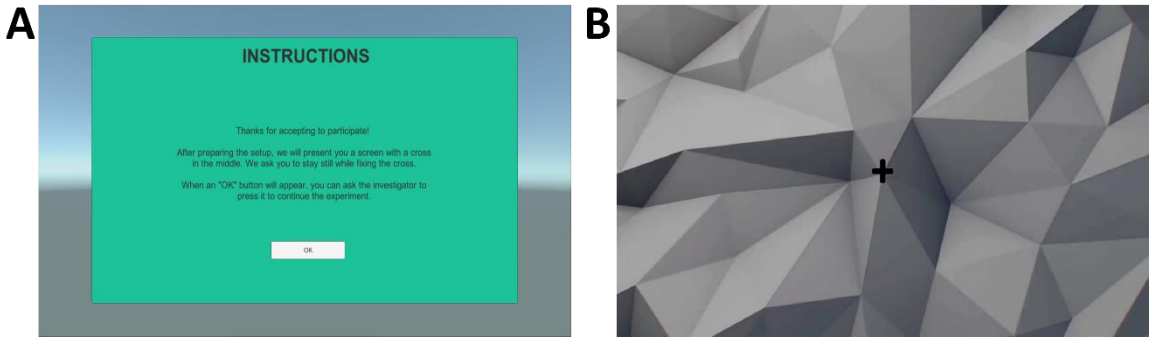


Figure 63: ***A)*** *Neutral State Video Instructions* ***B)*** *Neutral State Video screen.*

Training trials

After receiving the subject's consent to continue the experiment, the second instructions scene was read aloud by the experimenter (Figure 64 A). These instructions explained the upcoming short training sample used to show how the experimental session would have worked. This helped the subjects to become familiar with the task.

This scene contained different instructions regarding the task according to the assigned experimental condition:

- In the Slow Breathing (SB) condition, the subjects were asked to maintain the respiratory rate at a slow pace (about 6 breaths/minute) to make the virtual hand materialise (become visible) enough for feeling the energy of the sphere when it approached the virtual hand.

- In the Normal Breathing (NB) condition, the subjects were required to maintain the respiratory rate at a normal pace (about 14 breaths/minute) to achieve the same goal.

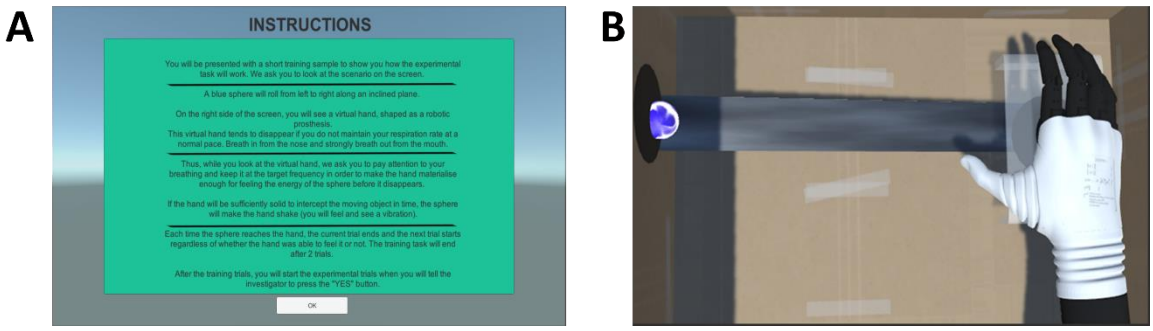


Figure 64: *Task instructions.*

By maintaining the right RR of the assigned condition (SB or NB) during the sliding of the energetic sphere (from the hole on the left wall to the hole under the *Hannes* 3D model) the participants were able to decrease the transparency of the virtual hand and to make it solid (Figure 64 B) enough to "feel" the energy of the approaching sphere through the vibration of the smartphone. This event meant that the trial was successfully accomplished.

Once the 2 training trials were completed, a textbox appeared to remind once again to pay attention to the breathing and to keep it at the target pace. It was then asked the subjects to tell the investigator to press "YES" if they felt ready to start the real experimental session or to press "NO" if they wanted to train again (Figure 65 A). There was no limit in the repetition of the training trials.

Experimental trials

Once the participants were ready to start the experimental session, after asking the experimenter to press the button "YES", the 16 experimental trials started, each one based on the animation and the respiratory biofeedback task described above (Figure 65 B).

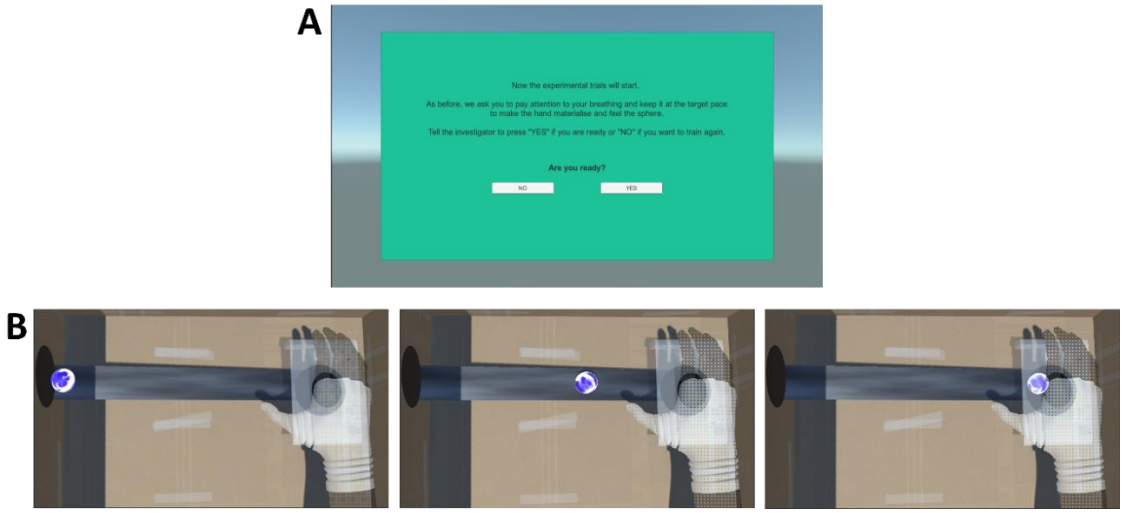


Figure 65: A) *POP UP scene and* ***B)*** *Evolution of the sliding sphere.*

Subjective questionnaire

Being completed the experimental trials, the subjective questionnaire scenes appeared instantaneously (Figure 66).

The experimenter read aloud the questionnaire instructions, asking the subjects to rate their experience during the session through a score from 1 (Total Disagreement) to 5 (Total Agreement), defining how much they disagreed/agreed with the 14 statements. These latter investigated different aspects regarding the VH ownership and the real hand disownership, as well as the overall experience (emotional engagement, stress, interoceptive intensity, perception of the relation between the virtual hand visibility and the breathing rate) The subjects read silently by themselves the statements (divided in 3 scenes) and told the investigator the different scores. To conclude, the experimenter asked the subjects to estimate the duration of the experimental session (in minutes) and filled the dedicated box on the screen with the subjects' answers.

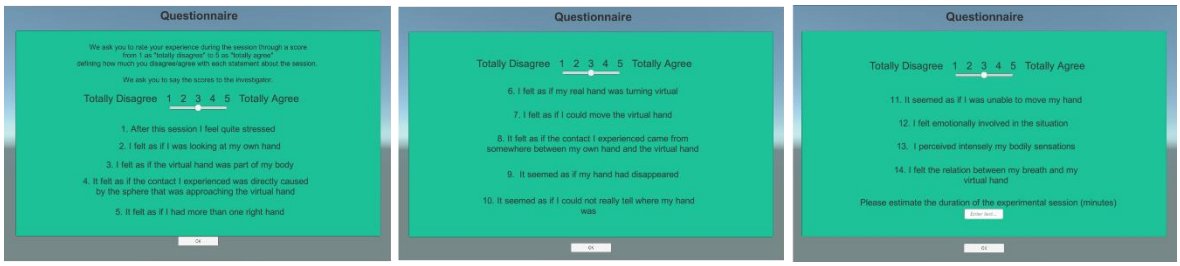


Figure 66: *Questionnaire.*

By clicking the "OK" button at the end of the questionnaire, the experimenter moved to another instructions scene concerning the neutral state final video. Finally, once the video was over and the cross substituted by the "FINISH" button the subjects could request the investigator to press it to end the experiment.

Proprioceptive drift

Before freeing the subjects by the whole surrounding setup the proprioceptive drifts were measured. The persons were asked to close their eyes, raise their right arm while holding the smartphone (after removing only the black blanket on this side) and to waving it around to stretch.

Then, they were asked to relocate the smartphone in the perceived initial position, always while keeping the eyes closed. The lateral distance between the actual position of the phone during the experiment (signed at the beginning while preparing the setup with a piece of tape) and the one estimated by the participants (without watching) were measured by the experimenter, together with the direction of the deviation.

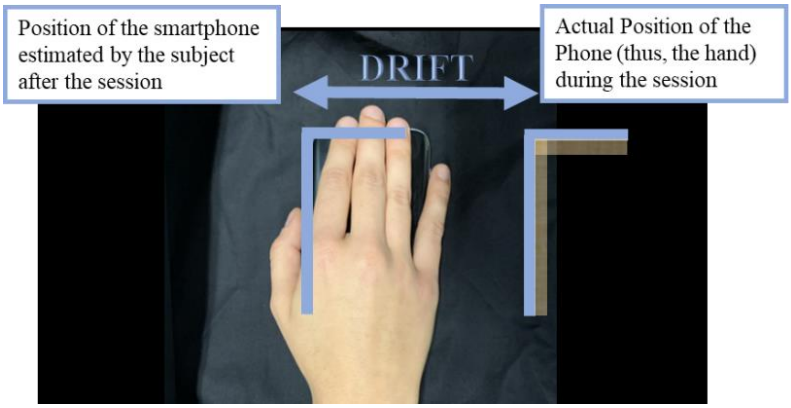


Figure 67: *Proprioceptive drift measurement.*

After this measurement the headphones and the blankets were removed and the subjects were free.

3 Results

In the following Chapter, the results obtained are reported. As for the Materials and methods, this Chapter is divided into two sections regarding, respectively, the pre-validation of the post market clinical trial and the pilot study on the embodiment stimulation.

In the first section the results of the pre-validation are presented separately based on the object of the evaluation (user experience, embodiment and functionality), as done with the methods in 2.2.1.2: Methods. For each subchapter tables with each subject's results are firstly reported. Then, trends over time and comparisons between the commonly used prosthesis and *Hannes* hand are shown through histograms.

In the second section, the results related to the experiment performed in the spatially augmented VR are exposed. The preliminary results obtained in the two experimental conditions are shown separately for the 12 healthy subjects and for the 2 amputees. In the healthy subjects section the averages are discussed, while in the amputees section the results are investigated singularly. Both qualitative (questionnaire) and objective (proprioceptive drift) measures were analysed to investigate the level of embodiment achieved during the experiment.

3.1 Pre-validation of the post market clinical trial results

As explained above, the pre-validation results are divided in three subchapters regarding user experience, embodiment and functionality. For each of subjects a different colour was assigned as shown in the following legend:

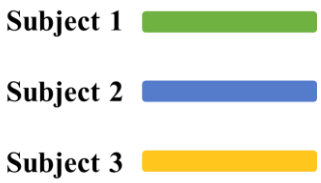


Figure 68: *Legend of the colours assigned to each subject.*

It is worth recalling that in TB the evaluation was conducted with the commonly used prosthesis (Subject 1: Bebionic; Subject 2: Variplus; Subject 3: Michelangelo), whilst from T1 to T4 with the *Hannes* prosthesis.

3.1.1 User experience

The evaluation of the UX was carried out through four different questionnaires. The overall indexes of the three validated questionnaires (Raw NASA-TLX, SUS, TAPES) are reported in Table 10, and shown in Figure 69, Figure 70 and Figure 71 respectively, in which the trend is highlighted with lines from T2 to T4.

For what concern the Ad hoc questionnaire, the last questionnaire used to evaluate the UX, it does not provide an overall index and hence it is treated differently.

Subject 1	TB	T2	T3	T4	T4-TB [%]
Raw NASA-TLX [%]	25,83	34,17	18,33	11,67	54,8
SUS [%]	70	95	100	100	42,9
TAPES [%]	70,83	80,00	85,83	93,33	31,8

Subject 2	TB	T2	T3	T4	T4-TB [%]
Raw NASA-TLX [%]	30,83	40,83	47,5	25,83	16,2
SUS [%]	87,5	87,5	92,5	90	2,9
TAPES [%]	80,83	83,33	89,17	93,33	15,5

Subject 3	TB	T2	T3	T4	T4-TB [%]
Raw NASA-TLX [%]	44,17	43,33	24,17	7,5	83,0
SUS [%]	75	95	95	100	33,3
TAPES [%]	96,67	96,67	95,00	96,67	0,0

Table 10: *User experience questionnaires results reported for Subject 1, Subject 2 and Subject 3 over time (TB, T2, T3, T4). The last column T4-TB [%] of the tables reports the percentage of improvement or deterioration of Hannes (T4) with respect to the commonly used prosthesis (TB) accordingly to formula (11). Green cells indicate an improvement, red cells a deterioration whilst yellow cells an equality.*

The three tables (see Table 10) of the validated questionnaires, investigating the UX, show a general improvement between T4 and TB for each subject and in each questionnaire, expect for Subject 3 who had a global TAPES score equal in TB and in T4.

Raw NASA-TLX questionnaire

The percentage of the raw NASA-TLX scores are shown in the histogram below (Figure 69). As it can be clearly seen in Figure 69, after a general little increase in T2 with respect to TB and a slight increment for Subject 2 in T3, each trend from T2 to T4 is descendant. After three months of use (T4) the scores obtained with *Hannes* are lower than the ones obtained with the reference hands (TB).

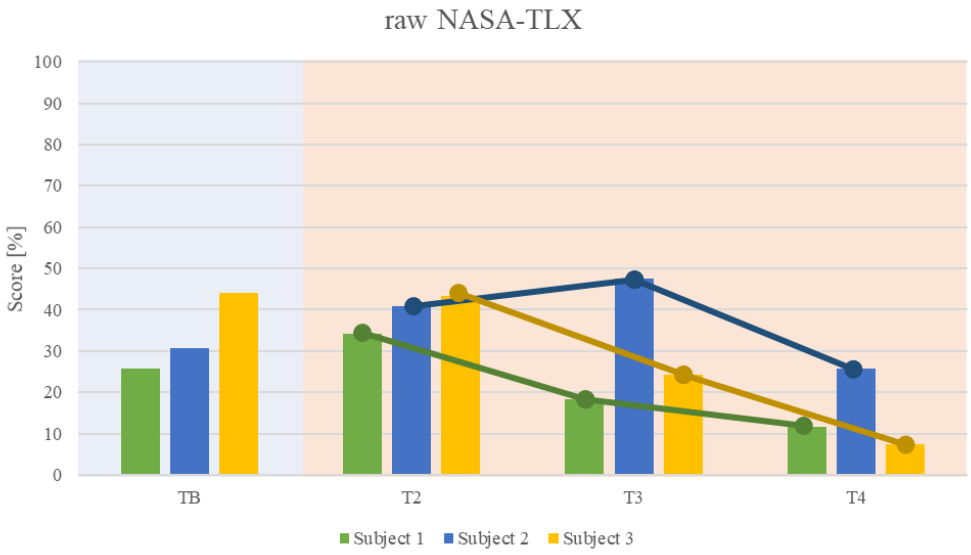


Figure 69: *raw NASA-TLX results for each subject over time (TB, T2, T3, T4). The light blue shaded area highlights the results obtained with the reference hand, whilst the light orange shaded area shows the results obtained with Hannes. The trend is highlighted by lines from T2 to T4.*

SUS questionnaire

The SUS histogram (Figure 70) shows the global scores as percentages in the vertical axis. Figure 70 immediately shows for each subject an improvement between TB and T2, then an ascending trend is observable for each subject over time, except for Subject 2 who had a very little decrease between T3 and T4. Subject 1 and 3 even obtained the maximum score in T4.

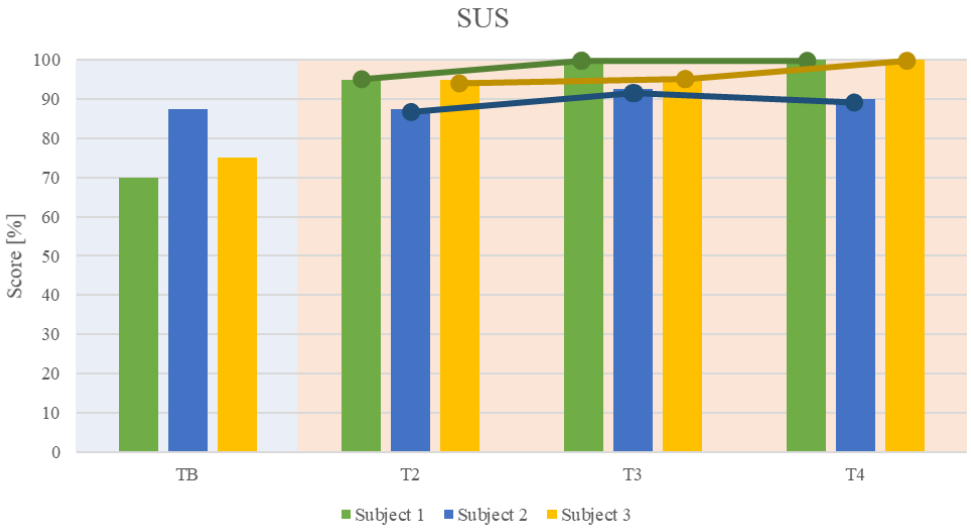


Figure 70: *SUS results for each subject over time (TB, T2, T3, T4). The light blue shaded area highlights the results obtained with the reference hand, whilst the light orange shaded area shows the results obtained with Hannes. The trend is highlighted by lines from T2 to T4.*

TAPES questionnaire

The TAPES sums transformed into percentage scores are reported in the histogram of Figure 71. Figure 71 shows an immediate increase from TB to T2 for Subject 1 and 2 and a maintenance for Subject 3. Subject 1 and 2 then exhibit a continuous positive trend over time, while Subject 3 has a little decrease between T2 and T3, before a new increase in T4. Subject 1 and 2 have a greater score in T4 compared to TB, whilst subject 3 obtained the same percentage.

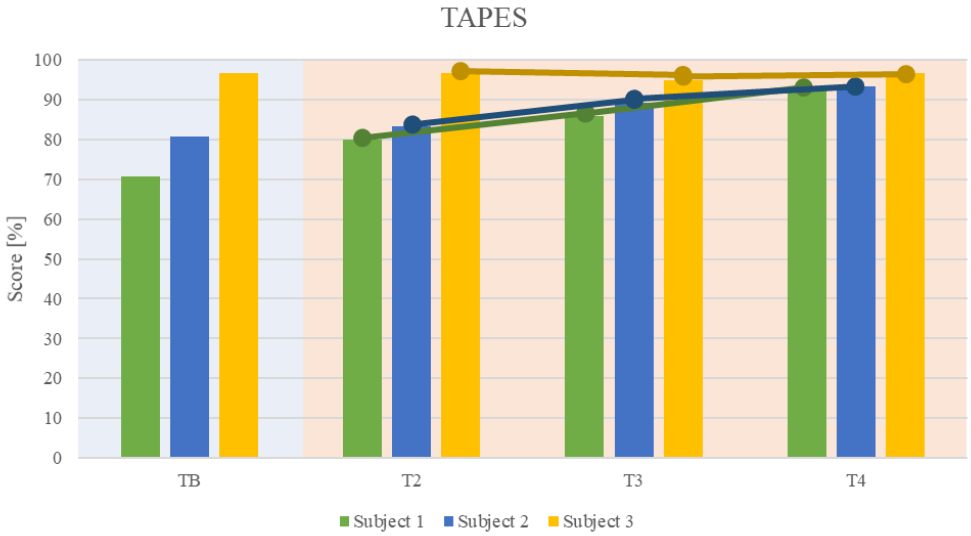


Figure 71: *TAPES results for each subject over time (TB, T2, T3, T4). The light blue shaded area highlights the results obtained with the reference hand, whilst the light orange shaded area shows the results obtained with Hannes. The trend is highlighted by lines from T2 to T4.*

Ad hoc questionnaire

The 22 items and their related scores of the ad hoc questionnaire are shown in Table 11 for each item and for each subject, since this questionnaire does not provide an overall comparable index. The scores are related to different colours accordingly to the following legend:

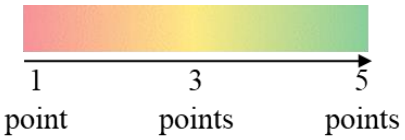


Figure 72: *Legend of the AD-HOC questionnaire.*

Low scores indicate a totally disagreement with the relative statement, while high scores indicate a totally agreement with the relative statement. It must be highlighted that the Ad hoc questionnaire evaluated the UX as well as the embodiment, thus it belongs also to the subchapter 3.1.2.1: Questionnaires.

Subject	1				2				3			
Time	TB	T2	T3	T4	TB	T2	T3	T4	TB	T2	T3	T4
1. It was hard to understand to perform during the activities	3	4	2	1	1	2	1	1	2	1	1	1
2. The possibility to adjust the thumb to the task was appreciable		5	5	3		4	4	4	5	5	5	5
3. The device fingers movement is pretty natural	2	5	5	4	4	5	4	4	3	5	5	5
4. I feel I can exploit the device at its best	4	4	5	5	4	3	4	4	5	5	5	5
5. I did not have any coordination problem in tasks which require both hands.	3	4	4	5	4	4	5	4	5	5	5	5
6. I think I can utilise the device in different daily contexts	4	5	5	5	4	4	4	4	5	5	5	5
7. The device usage improved my quality of life in terms of autonomy	4	5	5	5	4	3	4	4	5	5	5	5
8. I had to think about different strategies to perform tasks without involving the prosthetic hand	2	3	4	4	1	1	1	1	1	1	1	1
9. The possibility to adjust the wrist to the task is appreciable		5	5	5		4	4	4		5	5	5
10. I hesitated in using the device thinking about the errors I could have made.	2	4	4	2	1	1	1	1	1	1	1	1
11. I had to often adjust the thumb position in daily tasks	1	3	4	2		3	3	2	1	5	4	5
12. I frequentely used the position of the thumb in daily tasks	2	4	4	4	4	4	5	4	5	5	5	5
13. I managed to well coordinate the two hands using them together	2	4	4	5	4	5	5	4	5	5	5	5
14. The device brought positive changes in the relatins with others	4	4	5	5	2	3	4	4	5	5	5	5
15. I felt like the robotic hand was part of myself, incorporated in my person rather than a tool	1	4	4	4	4	3	3	4	5	5	5	5
16. I had to often adjust the wirst position in daily tasks		3	2	3		3	2	2	3	1	4	5
17. I felt to easily perceive the shape and the position of the grasped objects even whitout looking at them	2	4	2	2	3	4	4	4	3	3	3	5
18. I was immediately able to understand if an object was reachable or manipulable with the prosthesis	4	4	4	5	4	4	4	4	5	5	5	5
19. It seemed as the prosthesis was moving more indipendently than under my voluntary control	2	4	3	3	1	1	1	1	2	1	1	1
20. I think the device presents usage risks indipendentely by me	1	1	1	1	1	1	1	1	1	1	1	1
21. I think the device is improvable from a lot of perspectives	4	3	2	4	4	3	4	2	5	5	5	5
22. I see many more advantages than disadvantages in using this prosthesis with respect to the previous one				5				3				5

Table 11: *AD-HOC questionnaire for each subject over time (TB, T2, T3, T4).*

Low scores in the items 1, 8, 10, 11, 16, 19 and 20 indicate positive feedback, while the positive feedback is given by high scores in the remaining items. Blank-left cells indicate that the subject could not assigned a score to the relative statement because the prosthesis did not present the discussed feature. Table 10 shows different results among the subjects: from TB to T4 there is an overall improvement for subject 1 and 2, while the results of subject 3 are positive since the beginning and quite stable over the time. It is highlighted that from T2 no item was excluded by the evaluation. Item 15 explores the developed level of embodiment asking if the prosthesis is considered part of them rather than an external tool. The scores assigned to this item in the last session are very positive (4, 4 and 5 for each subject respectively). Item 21 investigates the feedback of the subjects about the

improvability of *Hannes*. The last item 22 indirectly asks the subjects if *Hannes* is preferable with respect to their previous prostheses. Subject 1 and 3 assigned the maximum score, while subject 2 gave a middle score. Both these last two items gave the subjects the possibility to add an open response where they could explain their considerations and justify their scores.

3.1.2 Embodiment

The embodiment of each subject was evaluated through different methods: questionnaires, proprioceptive tasks and the postural balance test. These methods are separately presented in the following subchapters.

3.1.2.1 Questionnaires

The scores assigned in the ad-hoc questionnaires (Ad-hoc UX and Embodiment questionnaire, RHI questionnaire) are shown for each item and for each subject, since they do not provide an overall index. The scores are related to different colours accordingly to the chosen range:

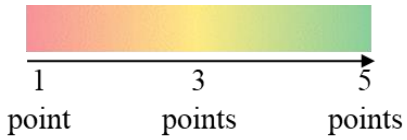


Figure 73: *Legend of the RHI questionnaire.*

Low scores indicate a totally disagreement with the relative statement, while high scores indicate a totally agreement with the relative statement.

This section is composed by the **Ad hoc** questionnaire already described in 3.1.1: User experience and the RHI questionnaire.

RHI questionnaire

The 15 items of the RHI questionnaire are reported in Table 12, showing the scores of each subject for each item in the different times of evaluation.

Subject	1					2					3				
Time	**TB**	**T1**	**T2**	**T3**	**T4**	**TB**	**T1**	**T2**	**T3**	**T4**	**TB**	**T1**	**T2**	**T3**	**T4**
1. I felt as if the prosthesis was my own hand	2	2	3	3	3	3	2	3	4	3	4	5	5	5	5
2. It seemed to feel the contact of the object	3	2	3	4	3	3	4	4	3	2	5	4	5	5	5
3. The prosthesis started to look like my own hand	2	2	3	3	3	4	2	3	3	2	4	4	5	5	5
4. The arm seemed to move towards the prosthesis	2	3	4	3	2	2	2	2	1	1	3	2	5	5	5
5. It seemed to have more than two arms	1	3	2	1	1	1	1	1	1	1	3	1	1	1	5
6. Also my hand started to look like «artificial»	3	2	3	2	3	1	2	1	1	1	1	1	1	4	5
7. It seemed like the prosthesis was moving towards the arm	2	2	3	4	1	1	2	2	1	1	3	1	1	5	5
8. I felt as the contact was coming from a point between the arm and the prosthesis	3	2	4	4	2	4	4	4	4	3	5	5	1	1	1
9. I felt like I could move the prosthesis and control it	1	1	2	3	3	2	2	2	1	1	2	3	5	5	5
10. Fixing the prosthesis it seemed to look directly at my own hand instead of a device	3	3	3	3	3	2	2	2	2	2	5	4	5	5	5
11. My arm seemed to be placed instead of the prosthesis	3	3	3	3	3	4	2	2	2	2	4	5	5	5	5
12. The prosthesis seemed to be part of my body	3	2	3	3	3	3	3	2	2	2	5	5	5	5	5
13. It seemed as if the contact I experienced was caused by the object	3	2	3	4	4	3	4	4	3	2	5	5	5	5	5
14. The prosthesis seemed to be placed instead of my arm	2	3	4	3	4	4	2	4	2	2	4	5	5	1	5
15. I felt the prosthesis belonging to me	2	2	3	4	4	3	3	4	2	2	5	5	5	5	5

Table 12: *RHI questionnaire for each subject over time (TB, T2, T3, T4).*

Some statements, such as the item 5 asking the subjects if they felt to have more than two arms, were added to control the participants' attention to the answering of the questionnaire and to exclude the hypothesis of an altered state. This questionnaire makes indirectly reference to the phantom-hand. Subject 3 assigned high scores since the beginning (TB), but he anyway had a small improvement over time. Differently, subjects 1 and 2 never assigned the maximum score to any statement with, from TB to T4, subject 1 showing a little improving mean trend, and subject 2 showing a worsening in the scores.

3.1.2.2 Proprioceptive tasks

The proprioceptive tasks results are separately reported in the Table 13. Values preceded by the sign "-" indicate proximal/inwards deviations, towards the body, while values marked with the sign "+" indicate distal deviations, towards the outside (Figure 74).

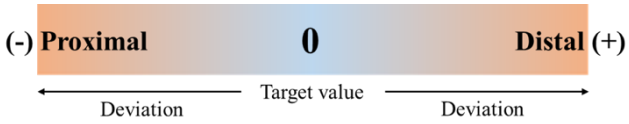


Figure 74: *Legend of the proprioceptive tables: nose, elbow, wrist and index task.*

The last three rows represent the bimanual proprioceptive task results (Below shoulders. Shoulders level, Above shoulders). In this case, values marked with the sign "+" indicate that one of the two hands was forward or upward with respect to the other one, while values preceded by the sign "-" mean the opposite (backward or downward) (Figure 75).

Figure 75: *Legend of the proprioceptive tables: below, at the level and above the shoulder task.*

Subject 1	Condition	TB	T1	T2	T3	T4
Nose [cm]	Prosthesis	3,5	2,5	1,2	1,2	0
	Controlateral hand	0	0	0	0	0
Elbow [cm]	Prosthesis	4	1	0	0	0
	Controlateral hand	0	0	0	0	-2
Wrist [cm]	Prosthesis	0	1,2	0	0	0
	Controlateral hand	0	0	0	0	-2
Index [cm]	Prosthesis	3,5	3	4,5	3	0
	Controlateral hand	5	4,5	0,8	0	-1
Below shoulders [cm]		0	1,5	2	2	0
Shoulders level [cm]		2	2	2	0	0
Above shoulders [cm]		1,5	2,5	3	0	0

Subject 2	Condition	TB	T1	T2	T3	T4
Nose [cm]	Prosthesis	-8	-8	-5	-2	-1
	Controlateral hand	0	0	0	0	-2
Elbow [cm]	Prosthesis	0	-1,7	0	0	0
	Controlateral hand	0	0	-1	0	0
Wrist [cm]	Prosthesis	-5	-1,3	-2	-4	-1
	Controlateral hand	-4,5	-5,5	-2,5	0	0
Index [cm]	Prosthesis	-5,5	-3,3	-4,5	-4	0
	Controlateral hand	-5,7	-6,3	-5	-5	-2
Below shoulders [cm]		0	0	0	3	-2
Shoulders level [cm]		0	0	-1	0	0
Above shoulders [cm]		0	0	-2	5	0

Subject 3	Condition	TB	T1	T2	T3	T4
Nose [cm]	Prosthesis	5	-5	0	0	0
	Controlateral hand	0	0	0	0	0
Elbow [cm]	Prosthesis	0	0	0	0	0
	Controlateral hand	0	0	0	0	0
Wrist [cm]	Prosthesis	0	0	0	0	0
	Controlateral hand	-1	-1,8	-3	0	0
Index [cm]	Prosthesis	1,7	-3	0	-7	0
	Controlateral hand	-1	-9	-5,5	0	0
Below shoulders [cm]		0	0	0	0	0
Shoulders level [cm]		0	0	0	0	0
Above shoulders [cm]		0	1,6	0	0	0

Table 13: *Proprioceptive results reported for Subject 1, Subject 2 and Subject 3 over time (TB, T1, T2, T3, T4).*

Each table show a general trend towards the 0 value, which was the ideal target. Subject 1 tended to overestimate the distances, generating mainly "positive" values. In the mono-manual tasks subject 1 performed better with the contralateral arm. For what concerns the bi-manual tasks, after an initial worsening between T1 and T2, they have improving trends,

reaching the 0 in the last session. Subject 2 instead tended to underestimate the distances, mainly leading to "negative" values. The first two mono-manual tasks were performed better with the prosthesis rather than the sounded arm, whilst the last two have general consistent deviations from the target 0 and precisely the worst deviations are obtained with the contralateral hand. Differently from subject 1, subject 2 performed better in the bi-manual tasks. The best improvement belongs to subject 3, who correctly performed each task in the last session (T4). In general subject 3 was more prone to underestimate the distances in the mono-manual tasks (there is only one "positive" value). The bi-manual tasks, except for one single little deviation above the shoulders, were perfectly conducted in each session.

3.1.2.3 Postural balance test

The result of each subject obtained by analysing data from the force balance using a custom-made Matlab script (Total TL, Medio-Lateral ML and Anterior-Posterior AP length paths) are reported in Table 14.

Subject 1	Condition	No prosthesis	TB	T1	T2	T3	T4	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	352,2	484,4	478,0	446,7	404,3	411,9	15,0	-16,9
	EC	559,3	630,5	589,8	501,3	554,8	479,4	24,0	14,3
ML [mm]	EO	162,8	229,0	222,1	210,8	195,4	177,2	22,6	-8,9
	EC	249,0	285,5	270,4	238,9	218,6	177,2	37,9	28,8
AP [mm]	EO	280,5	377,6	357,0	349,7	310,0	334,9	11,3	-19,4
	EC	447,1	497,4	438,6	390,3	464,1	410,9	17,4	8,1

Subject 2	Condition	No prosthesis	TB	T1	T2	T3	T4	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	371,6	521,1	482,7	506,4	500,7	485,4	6,9	-30,6
	EC	721,9	878,8	665,7	655,7	808,2	749,9	14,7	-3,9
ML [mm]	EO	155,1	239,1	251,4	192,4	186,2	173,5	27,4	-11,9
	EC	322,6	413,5	323,7	245,7	387,9	336,0	18,7	-4,1
AP [mm]	EO	307,8	413,3	360,3	438,2	433,5	397,3	3,9	-29,1
	EC	582,7	689,9	514,7	568,3	638,8	573,3	16,9	1,6

Subject 3	Condition	No prosthesis	TB	T1	T2	T3	T4	T4-TB [%]	T4 vs Noprot [%]
TL [mm]	EO	1058,6	1095,3	959,6	890,1	896,5	847,0	22,7	20,0
	EC	1790,9	2030,4	2293,3	1833,9	1800,2	1764,0	13,1	1,5
ML [mm]	EO	873,7	878,5	648,7	617,2	626,6	604,8	31,2	30,8
	EC	1409,6	1564,7	1715,7	974,2	1111,3	995,8	36,4	29,4
AP [mm]	EO	439,5	490,4	573,7	511,9	527,2	503,6	-2,7	-14,6
	EC	855,3	984,6	1180,0	1348,8	1181,3	993,0	-0,9	-16,1

Table 14: *Postural balance results reported for Subject 1, Subject 2 and Subject 3 over time (TB, T1, T2, T3, T4). The second column specifies the condition (Eyes Opened EO or Eyes Closed EC), the third one regards the acquisition of the data without any kind of prosthesis, carried out in correspondence of TB. The last two columns show the percentage of improvement or deterioration of Hannes (T4) with respect to the commonly used prosthesis (TB) and to the absence of any prosthesis (No prosthesis). Accordingly to formula (11) green cells indicate an improvement, whilst red cells a deterioration.*

From the second to last column of the tables it can be easily observed that, for each patient, there is an improvement obtained with *Hannes* in T4 with respect to the commonly used

prosthesis evaluated in TB, except for a minimal deterioration in the Anterior Posterior sway of subject 3. On the other hand the comparison between the results obtained with *Hannes* in T4 and the results obtained with the absence of any prosthesis shows a deterioration in most of the variables. Subject 1 presents variable results, subject 2 only had a slight improvement in the Anterior Posterior direction with the eyes closed, whilst subject 3 presents an improvement in the Total and Medio-Lateral path lengths in both conditions and a deterioration in the Anterior-Posterior path length in both conditions.

The histograms of Figure 76, Figure 77 and Figure 78 show the total (TL), medio-lateral (ML) and anterior-posterior (AP) path lengths of each subject.

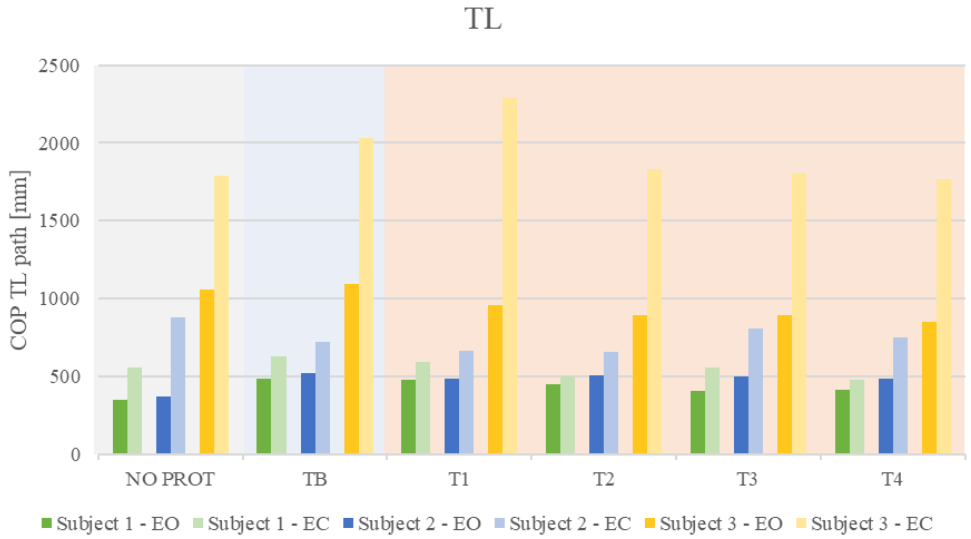


Figure 76: *Total path length results for each subject over time (NO PROT, TB, T1 T2, T3, T4). The light grey shaded area highlights the results without any prosthesis (TB), the light blue shaded area the results at TB with the commercial prosthesis, whilst the orange shaded area highlights the T1 – T4 sway with Hannes hand. Two columns are associated to each subject, showing the results obtained in the two investigated conditions (EO and EC) over time. Precisely, dark colours refer to the EO condition results, whilst light colours to the EC condition results.*

The Total length path histogram shows a large variability among the subjects. It is immediately evident that subject 3 stands out from the other 2 subjects presenting higher total postural oscillations. Subject 1 and 2 have similar results. Between T1 and T4 a descending trend is appreciable for subject 1 and 3 in each condition, except for a slight increment between T2 and T4 for subject 1 in the EC condition), immediately restored in T4. Subject 2 shows an almost constant trend for the EO condition) and a slightly ascending trend for the EC condition). Comparing T4 with the results obtained in the absence of any prosthesis ("NO PROT") it is observable a little increase in the EO condition for subject 1 and 2 and a little decrease for subject 3. In the EC condition subject 1 shows a reduction, while subject 2 and 3 present similar results. All subjects present decreased sway in both conditions comparing the results of *Hannes* in T4 with the results obtained with the commonly used prosthesis in TB.

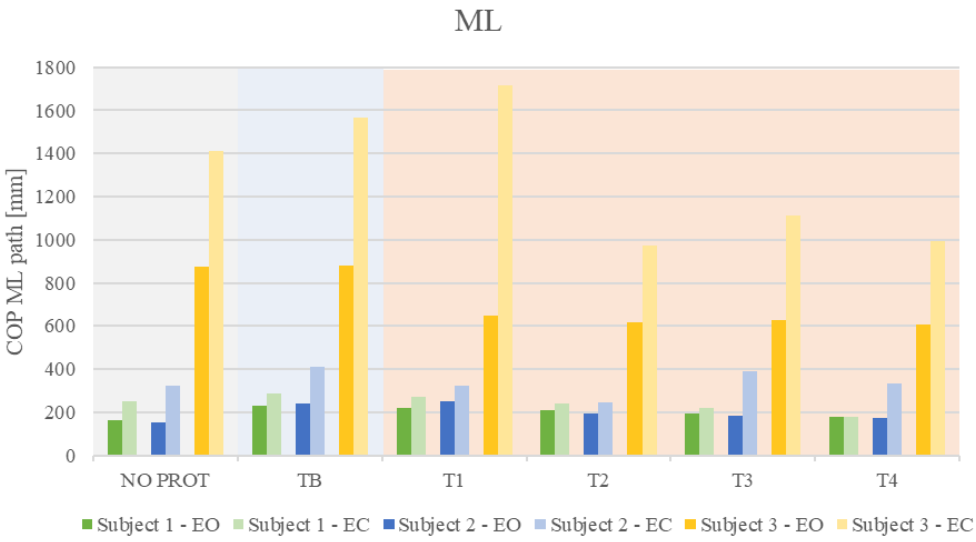


Figure 77: *Medio Lateral path length results for each subject over time (NO PROT, TB, T1 T2, T3, T4). The light grey shaded area highlights the results without any prosthesis (TB), the light blue shaded area the results at TB with the commercial prosthesis, whilst the orange shaded area highlights the T1 – T4 sway with Hannes hand. Two columns are associated to each subject, showing the results obtained in the two investigated conditions (EO and EC) over time. Precisely, dark colours refer to the EO condition results, whilst light colours to the EC condition results.*

Also in the Medio-Lateral results there is a large difference between the subjects' results. Again subject 3 differs because of his high oscillations, higher in the EC condition. From T1 to T4 the sway of subject 1 slightly decrease in both conditions. Subject 2 has a continuous descending trend for what concerns the EO condition, while subject 3 maintains almost the same results with a very slight decrease. In the EC condition the trend of both subject 2 and 3 is descending in T1 and T2 then it presents an increment after which it starts again its decline. The oscillations in EO condition are slightly higher for subject 1 and 2 in T4 with *Hannes* with respect to the ones without any prosthesis ("NO PROT"), whilst they are definitely lower for subject 3. In the EC condition these are lower for subject 1 and 3 and basically equal for subject 2. Comparing T4 with TB it can be observed that all subjects' results are lower in both conditions.

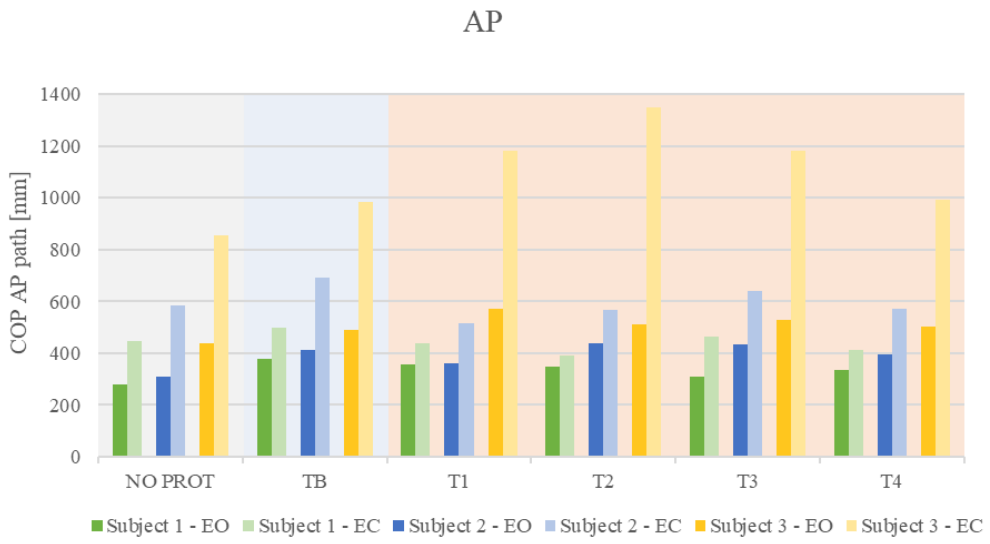


Figure 78: *Anterior Posterior path length results for each subject over time (NO PROT, TB, T1 T2, T3, T4). The light grey shaded area highlights the results without any prosthesis (TB), the light blue shaded area the results at TB with the commercial prosthesis, whilst the orange shaded area highlights the T1 – T4 sway with Hannes hand. Two columns are associated to each subject, showing the results obtained in the two investigated conditions (EO and EC) over time. Precisely, dark colours refer to the EO condition results, whilst light colours to the EC condition results.*

The Anterior-Posterior oscillations confirm the large variability between the subjects. In this case the deviations of subject 3 are less consistent with respect to the ML and TL results. From T1 to T4 subject 1 has a descending trend in the EO condition with a slight final increment in T4, while in the EC condition the trend is descending, it rises in T3 and again decreases in T4. Subject 2 has a bell-shaped (very large) trend in both conditions. Its oscillations increase from T1 to T3 and then decrease. Subject 3 has an almost continuous descending trend in the EO condition (except for a minimal increment in T3) and a continuous descending trend in the EC condition from T2 after an initial increase between T1 and T2. The sway of each subject in T4 and in the EO condition are higher than the ones acquired without the prosthesis ("NO PROT"). The same regards the sway of subject 3 in the EC condition, while for subject 1 and 2 in this condition the oscillations are lower. The oscillations in T4 in both conditions are lower than the ones in TB for subject 1 with Bebionic and 2 with Varipuls, while are almost equal for subject 3 with Michelangelo.

3.1.3 Functionality

The scores of the functional tests (MMDT-P, SHAP, BBT) are shown in Table 15 and the scores of the functional questionnaires (QuickDASH, OPUS-UEFS) in Table 16. The trends in time are hence reported through histograms (Figure 79, Figure 80, Figure 81, Figure 82, Figure 83) and highlighted with lines from T1 to T4.

Subject 1	TB	T1	T2	T3	T4	T4-TB [%]
MMDT-P [s]	155	180	170	165	150	3,2
SHAP IoF [%]	75	58	64	72	76	1,3
SHAP Spherical [%]	80	66	78	83	87	8,8
SHAP Tripod [%]	64	73	67	72	68	6,3
SHAP Power [%]	73	56	62	72	77	5,5
SHAP Lateral [%]	72	47	55	59	59	-18,1
SHAP Tip [%]	53	37	42	43	47	-11,3
SHAP Extension [%]	80	64	72	78	82	2,5
BBT [blocks]	21	18	23	21	24	14,3

Subject 2	TB	T1	T2	T3	T4	T4-TB [%]
MMDT-P [s]	177	196	169	179	169	4,5
SHAP IoF [%]	66	61	70	75	79	19,7
SHAP Spherical [%]	68	72	86	86	90	32,4
SHAP Tripod [%]	70	56	57	64	78	11,4
SHAP Power [%]	57	60	68	74	89	56,1
SHAP Lateral [%]	69	53	61	63	64	-7,2
SHAP Tip [%]	52	29	31	40	43	-17,3
SHAP Extension [%]	78	61	81	87	87	11,5
BBT [blocks]	13	16	20	21	21	61,5

Subject 3	TB	T1	T2	T3	T4	T4-TB [%]
MMDT-P [s]	159	174	198	180	175	-10,1
SHAP IoF [%]	73	59	73	69	74	1,4
SHAP Spherical [%]	77	73	78	83	79	2,6
SHAP Tripod [%]	76	46	61	65	66	-13,2
SHAP Power [%]	76	55	71	79	78	2,6
SHAP Lateral [%]	66	54	73	59	71	7,6
SHAP Tip [%]	46	29	38	28	49	6,5
SHAP Extension [%]	82	63	72	70	75	-8,5
BBT [blocks]	14	16	17	20	22	57,1

Table 15: *Functional tests results reported for Subject 1, Subject 2 and Subject 3 over time (TB, T1, T2, T3, T4). The last column T4-TB [%] shows the percentage of improvement or deterioration of Hannes with respect to the commonly used prosthesis (investigated in TB) accordingly to the formula (11). Green cells indicate an improvement, red cells a deterioration and yellow cells an equality.*

Subject 1	TB	T2	T3	T4	T4-TB [%]
QuickDASH [%]	31,8	11,4	11,4	18,2	42,8
OPUS-UEFS: usage [%]	71,43	50	57,14	75	5,0
OPUS-UEFS: goodness [%]	57,5	71,43	50	52,38	

Subject 2	TB	T2	T3	T4	T4-TB [%]
QuickDASH [%]	13,6	13,6	20,5	11,36	16,5
OPUS-UEFS: usage [%]	64,714	67,86	60,714	71,429	10,4
OPUS-UEFS: goodness [%]	51,47	51,32	58,82	43,75	

Subject 3	TB	T2	T3	T4	T4-TB [%]
QuickDASH [%]	2,3	6,8	4,5	2,27	1,3
OPUS-UEFS: usage [%]	64,29	82,14	75	64,28	0,0
OPUS-UEFS: goodness [%]	63,89	48,91	52,38	72,22	

Table 16: *Functional questionnaires results reported for Subject 1, Subject 2 and Subject 3 over time (TB, T2, T3, T4). The last column T4-TB [%] shows the percentage of improvement or deterioration of Hannes with respect to the commonly used prosthesis (investigated in TB) accordingly to the formula (11). Green cells indicate an improvement, red cells a deterioration and yellow cells an equality. Regarding the OPUS-UEFS questionnaire, the Δgoodness [%] between T4 and TB is not reported because considered not pertinent, since the respective values refer to different percentages of usage and hence are not comparable.*

Having regards to these tables it is clear that in general *Hannes* hand presented better results in T4 compared to the commonly used prosthesis in TB, as highlighted by the last column. Subject 1 and 2 both only have a deterioration in the scores of the SHAP Lateral and SHAP Tip grasps. Subject 3 instead presents a worsening in the MMDT-P test's score and in the scores of the SHAP Tripod and SHAP Extension grasps. Furthermore, he is neither improved nor worsened relating to the percentage of usage calculated in the OPUS-UEFS questionnaire, as highlighted by the equality obtained by the comparison.

MMDT-P

The MMDT-P seconds spent to complete the task are reported in the histogram of Figure 79.

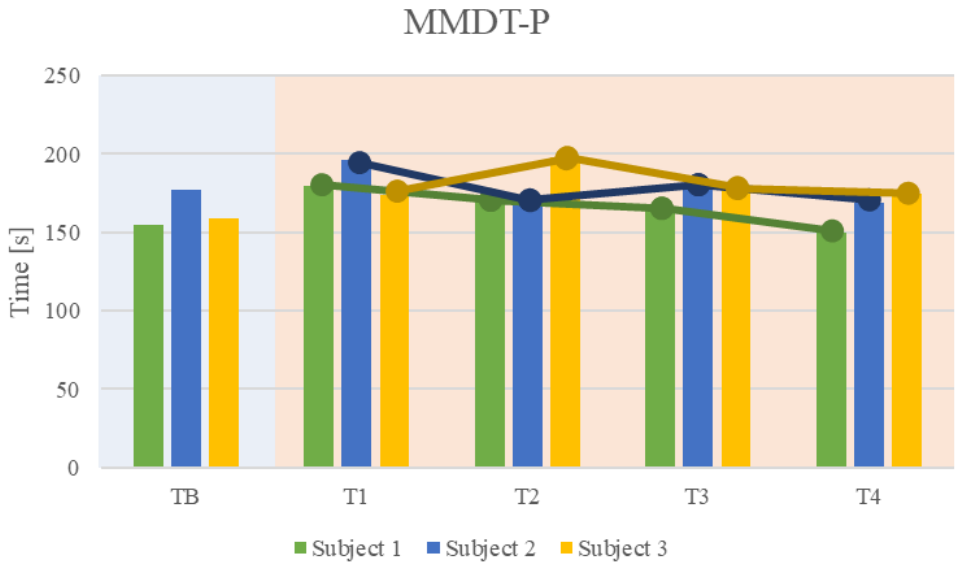


Figure 79: *MMDT-P results for each subject over time (TB, T1, T2, T3, T4). The light blue shaded area highlights the performances at TB with the commercial prosthesis whilst the orange shaded area highlights the T1 – T4 performances with Hannes hand. The trend is highlighted by lines from T1 to T4.*

From T1 to T4, while using *Hannes*, subject 1 decreased the time spent to complete the task, hence showing a continuous descending trend. Subject 2 had more ups and downs. Both these subject in T4 reached lower results compared to TB with Bebionic and Variplus hand respectively. Subject 3 after an initial increment between T1 and T2 shows a descending trend. Differently from the other two subjects, in T4 the time obtained with *Hannes* is higher than the one obtained with Michelangelo.

SHAP

The times acquired during the experimental session were used to calculate the 6 percentage of correct prehensile grips (SHAP Spherical, SHAP Tripod, SHAP Power, SHAP Lateral, SHAP Tip, SHAP Extension). Finally, an overall index of functionality was extracted from these 6 results (SHAP IoF). Each IoF value was automatically calculated with the SHAP software and reported in the histogram of Figure 80 accordingly to the vertical axis.

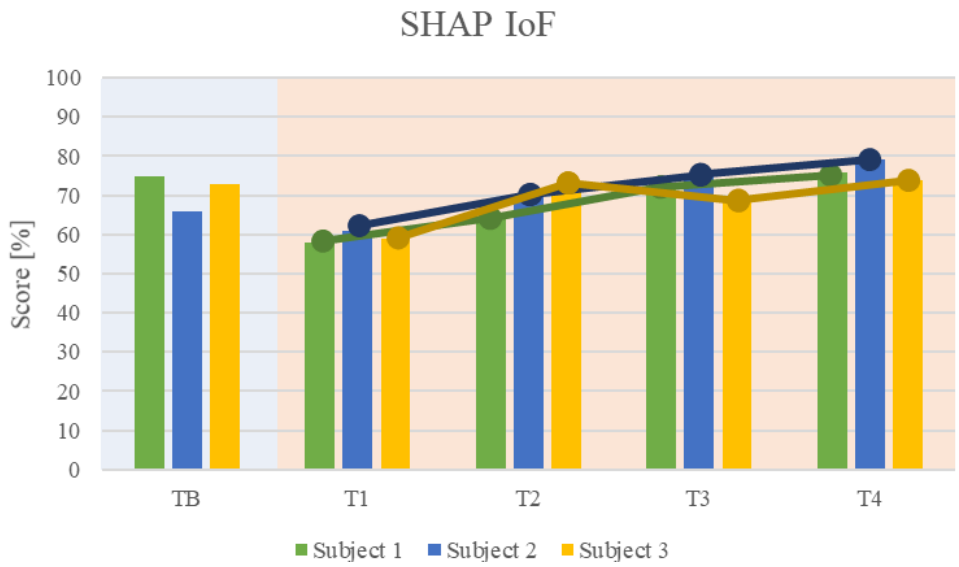


Figure 80: *SHAP IoF results for each subject over time (TB, T1, T2, T3, T4). The light blue shaded area highlights the performances at TB with the commercial prosthesis whilst the orange shaded area highlights the T1 – T4 performances with Hannes hand. The trend is highlighted by lines from T1 to T4.*

Subject 1 and subject 2 both present an ascending continuous trend from T1 to T4. Subject 3 had a slight deterioration in T3. Subject 2 shows the best improvement comparing *Hannes* in T4 with Variplus in TB. The improvement of subject 1 and 3 with *Hannes* in T4 with respect to Bebionic and Michelangelo in TB was minimal.

BBT

The number of transferred blocks during the 1-minute trial in the BBT functional test are shown in the histogram of Figure 81.

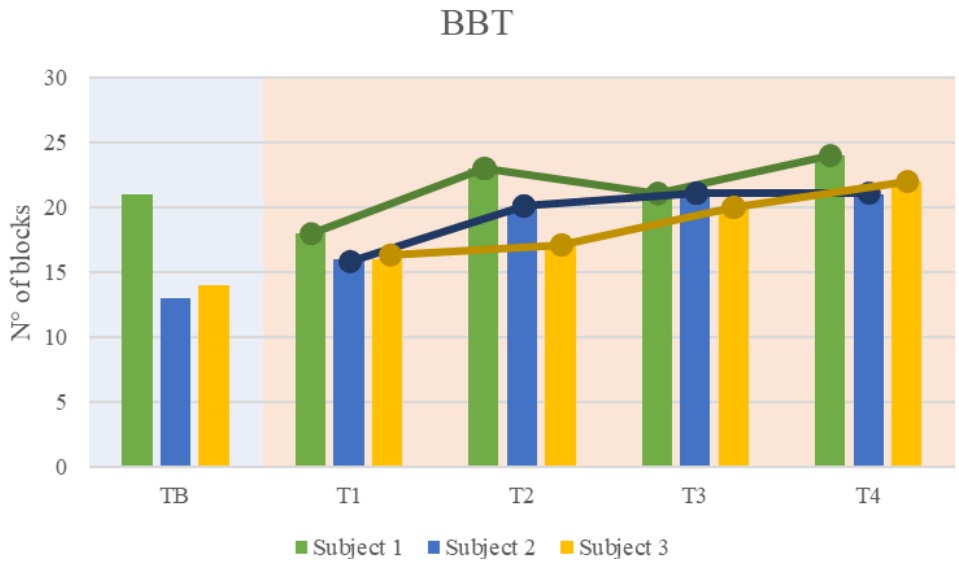


Figure 81: *BBT results for each subject over time (TB, T1, T2, T3, T4). The light blue shaded area highlights the performances at TB with the commercial prosthesis whilst the orange shaded area highlights the T1 – T4 performances with Hannes hand. The trend is highlighted by lines from T1 to T4.*

Subject 2 and 3 start in T1 with higher scores than in TB (with Variplus and Michelangelo respectively) and then have an ascending trend over time with *Hannes* (T1-T4). Subject 2 seems to reach a plateau. Subject 1 after an initial decrease from TB with Bebionic to T1 presents an increase, followed by a slight decrement and again by an increment. All subjects transported more blocks in T4 with *Hannes* than in TB with the commercial prostheses.

QuickDASH questionnaire

The overall indexes calculated from the QuickDASH functional questionnaire are presented in the histogram of Figure 82. The scores are reported as percentages in the vertical axis.

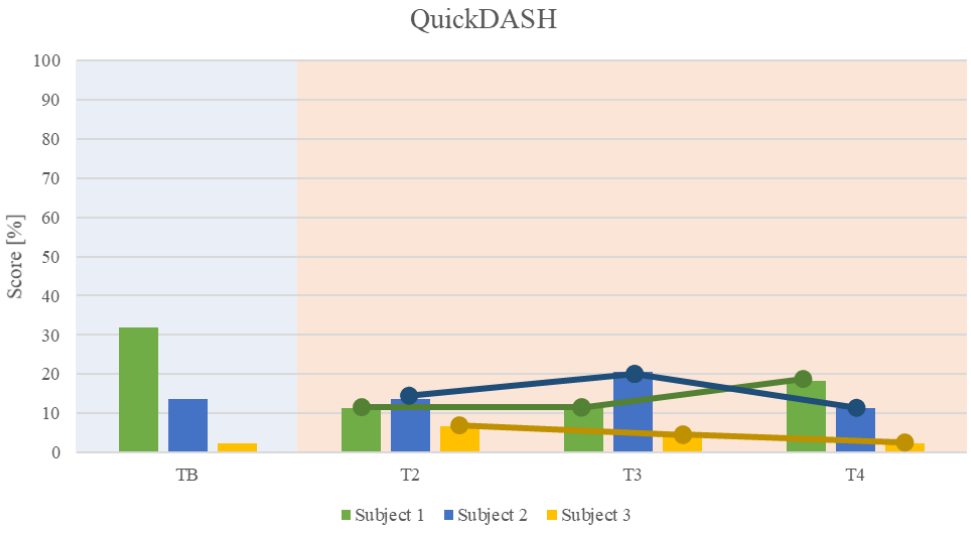


Figure 82: *QuickDASH results for each subject over time (TB, T1, T2, T3, T4). The light blue shaded area highlights the performances at TB with the commercial prosthesis whilst the orange shaded area highlights the T1 – T4 performances with Hannes hand. The trend is highlighted by lines from T1 to T4.*

Subject 1 has an ascending trend between T2 and T4, but the QuickDASH percentage score obtained in T4 referring to *Hannes* is anyway lower than the one of TB, having regards to Bebionic. Subject 2's score increases in T3 and decreases in T4 resulting lower than the score in TB with Variplus. Subject 3 has instead a continuous descending trend over time with *Hannes* (T2-T4) and in T4 the score is slightly lower than the one obtained in TB with Michelangelo.

OPUS-UEFS questionnaire

The OPUS-UEFS histogram of Figure 83 shows the percentage of prosthesis usage (light colour) and its related goodness (dark colour).

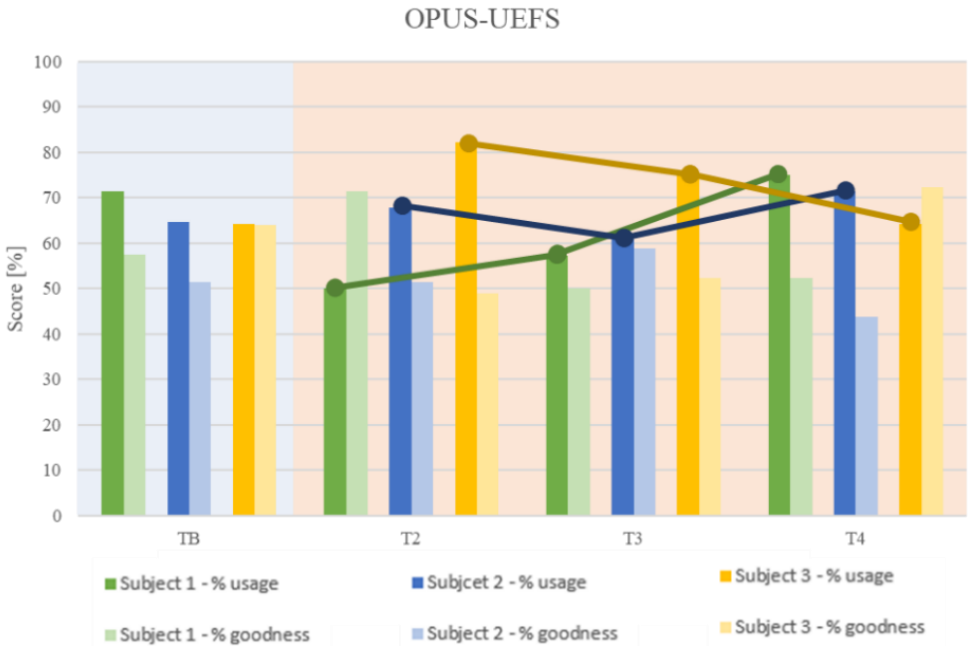


Figure 83: *OPUS-UEFS results for each subject over time (TB, T1, T2, T3, T4). The light blue shaded area highlights the performances at TB with the commercial prosthesis whilst the orange shaded area highlights the T1 – T4 performances with Hannes hand. Dark colours indicate the % of usage, whilst light colour the related goodness. The trend of the usage is highlighted by lines from T1 to T4.*

Subject 1 presents an ascending trend relating to the percentage of usage between T2 and T4 with *Hannes.* In T2, the first goodness of the first percentage of usage is quite high, while the goodness related to the higher percentages of usage is lower. Subject 2 shows a decrease in the percentage of usage in T3 but with a higher related goodness, then in T4 the percentage of usage increases and the related goodness decreases. Subject 3's percentage of usage has a descending trend over time, whilst the percentage of goodness increases. It can be observed that the percentages of usage in T4 (referring to *Hannes*) for subject 1 and subject 2 are slightly higher than the ones in TB (referring to Bebionic and Variplus). Subject 3 obtained the same percentage of usage with *Hannes* in T4 and Michelangelo in TB.

3.2 Embodiment stimulation - pilot study results

The results of the feasibility pilot study on the embodiment stimulation are separately shown for the 12 healthy subjects and the 2 amputees who participated to the study.

3.2.1 Healthy subjects

The healthy subjects' results are shown as averages.

Two different colours were assigned to the two experimental conditions as in the following legend:

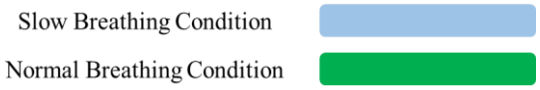


Figure 84: *Colour legend of the two experimental conditions.*

The average breaths per trial (and hence per minute) of the two experimental conditions for the 16 experimental trials and the 12 subjects are graphically reported in Figure 85. The number of breaths of each subject was obtained for each trial with the list of breathing events recorded in the txt file generated by the Unity software.

The blue continuous line of Figure 85 shows the average frequency maintained during the 16 trials for the Slow Breathing condition. The light blue shaded area shows the average standard deviation, which slightly decreases over the trials. The average RR for the 16 SB condition trials and the 12 subjects is 6,3 ± 2,8 breaths/minute, very close to the requested target one (6 breaths/minute), shown in Figure 85 as the blue dotted line.

The green continuous line of Figure 85 shows the average frequency maintained during the 16 trials for the Normal Breathing condition. The light green shaded area shows the average standard deviation, which considerably decreases. The average RR for the 16 NB condition trials and the 12 subjects is 11 ± 3,6 breaths/minute, lower than the requested target rate (14 breaths/minute), shown in Figure 85 as the green dotted line.

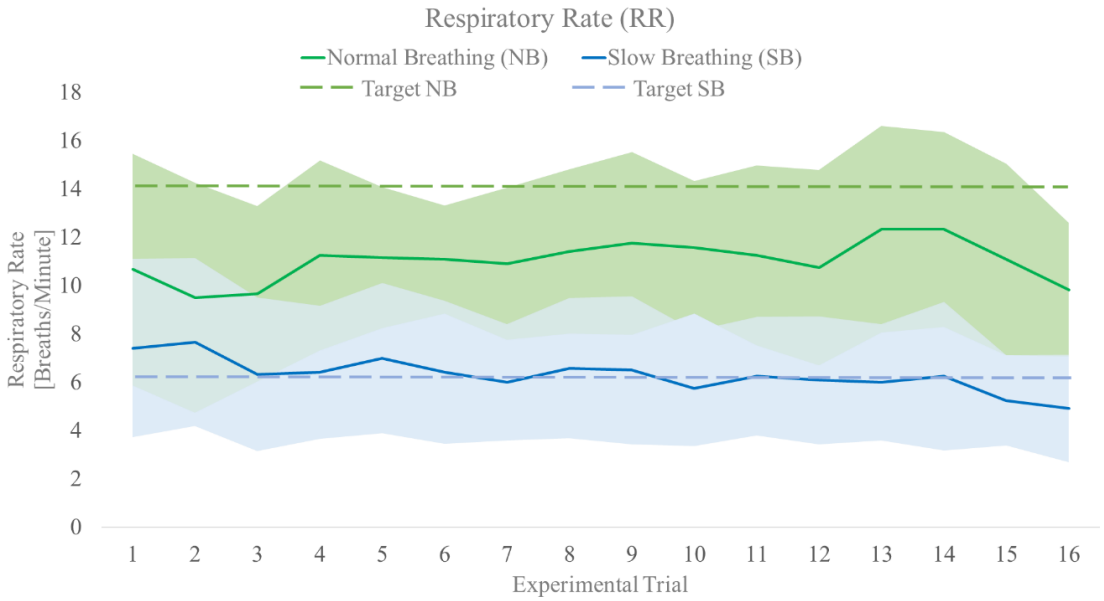


Figure 85: *Average respiratory rate based on condition, with standard deviation.*

The success rate (Figure 86) (number of vibrations produced during the experimental session) was calculated. In the NB condition the subjects made the virtual hand shake averagely the 65,1% ± 33,3% of the entire experimental session (about 10,4 ± 5,3 correct trials over 16). In the SB condition the average success rate was equal to the 59,9% ± 21% (about 9,6 ± 3,4 accomplished trials on 16).

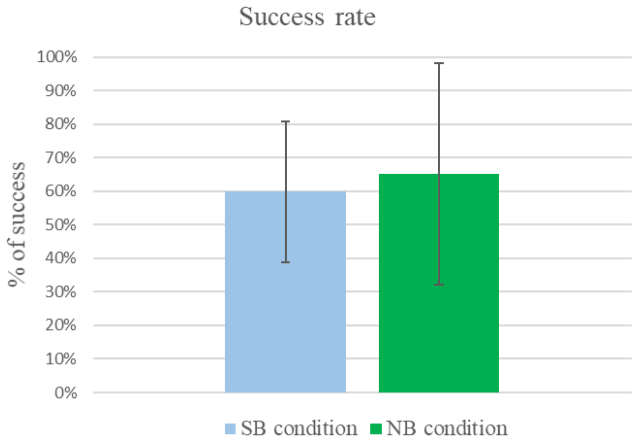


Figure 86: *Average percentage of success rate of the 16 experimental trials based on condition, with standard deviation.*

In Table 17 the post-session subjective questionnaire is reported with the medians, means and standard deviations of each statement' score for each condition (Slow Breathing and Normal Breathing). The first column indicates the type of the corresponding scales. The control scales were included to check the subject's compliance with the experimental instructions [70]. The last column shows, for each item, the difference between the scores of the means. Two scales (scale 3 and 4) belonging to the "Body ownership" sphere resulted

to give a significant difference in favour of the Slow Breathing Condition. The participants felt stronger the ownership of the virtual hand to their body (Scale 3, p=0,005) and that the vibration they experienced was directly caused by the approaching of the sphere to the virtual hand (Scale 4, p=0,004) when maintaining a Slow respiratory rate. These two significant differences for the Wilcoxon signed-rank test are highlighted in Table 17 with orange shaded boxes.

Scale type	N	Questionnaire Items	Slow Breathing			Normal Breathing			(SB-NB)	
			mdn	m	sd	mdn	m	sd	Δm	
Experience	1	After this session I feel quite stressed	2	2,33	1,16	3	3,25	0,75	-0,92	
Body ownership	2	I felt as if I was looking at my own hand	2	2,17	0,56	2	1,92	0,29	0,25	
	3	I felt as if the virtual hand was part of my body	3	2,67	0,49	2	1,83	0,58	0,83	*
	4	It felt as if the contact I experienced was directly caused by the sphere that was approaching the virtual hand	3	3,25	0,75	2	2,17	0,94	1,08	*
Control	5	It felt as if I had more than one right hand	1	1,5	0,80	1,5	1,67	0,78	-0,17	
	6	I felt as if my real hand was turning virtual	2	1,83	0,39	2	1,92	0,67	-0,08	
	7	I felt as if I could move the virtual hand	2	2	0.60	2	1,83	0,58	0,17	
	8	It felt as if the contact I experienced came from somewhere between my own hand and the virtual hand	2	1,75	0,76	2	1,92	0,52	-0,17	
Body disownership	9	It seemed as if my hand had disappeared	2	2,17	0,84	2	2,33	0,89	-0,17	
	10	It seemed as if I could not really tell where my hand was	3	2,42	0,80	2	2,33	0,99	0,08	
	11	It seemed as if I was unable to move my hand	3	2,67	0,78	2	2,33	0,89	0,33	
Experience	12	I felt emotionally involved in the situation	3	2,83	1,03	3	2,92	0,9	-0,08	
	13	I perceived intensely my bodily sensations	3	2,75	1,14	3	3,08	0,9	-0,33	
	14	I felt the relation between my breath and my virtual hand	3	2,75	1,36	3,5	3,33	1,16	-0,58	

Table 17: *Post-session subjective questionnaire with mean scores, medians and standard deviation. * means that the p of the Wilcoxon signed-ranked test between Slow and Normal Breathing condition was <0,05.*

The duration of the two experimental conditions was the same and equal to 16 minutes (16 trials of 1 minute each). For the SB condition the average time estimation of the 12 healthy subjects was 9,8 ± 4,3 minutes, whilst for the NB condition it was 11,1 ± 3,6 minutes (Figure 87). Hence, both the mean time estimations were lower than the real duration.

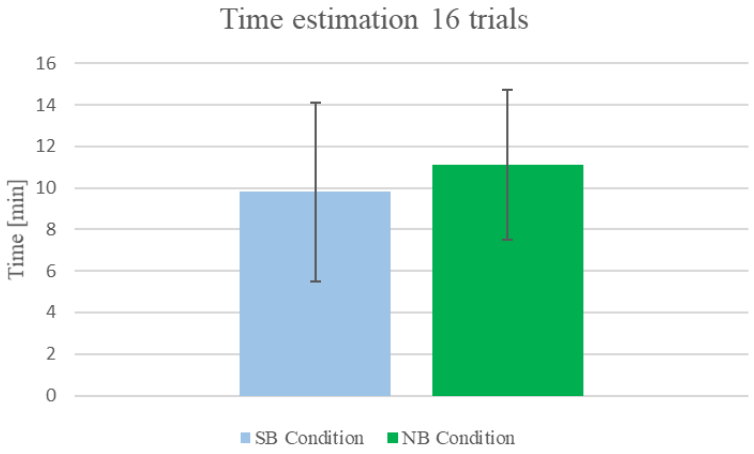


Figure 87: *Average time estimation of the 16 experimental trials based on condition, with standard deviation.*

The average proprioceptive drift (Figure 88) measured at the end of the experiment was 0,97 ± 3 cm towards left for the SB condition and 1,57 ± 2,93 cm towards right for the NB condition. The difference between the two average drifts (of the two conditions) was found to be significant with p=0,016.

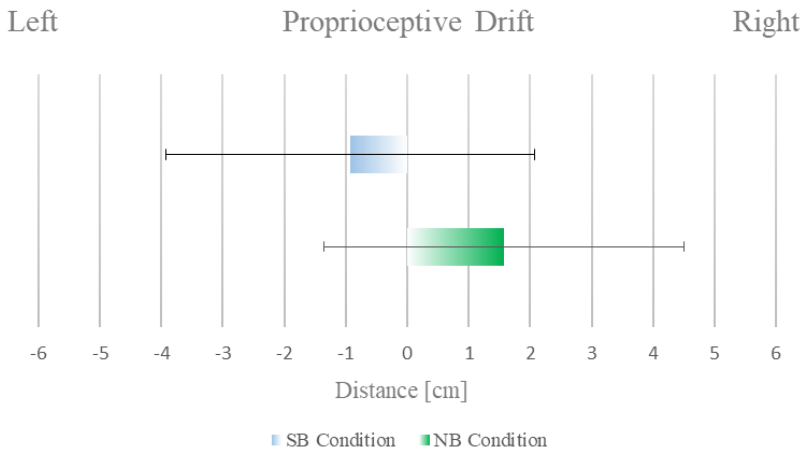


Figure 88: *Average proprioceptive drift based on condition, with standard deviation.*

3.2.2 Amputees

No statistical tests could have been applied to the amputees' results since the sample size was too small. The results of each amputee are purely shown.

In this section, two different colours were assigned to identify the two amputees, as shown in the following legend:

Figure 89: *Colour legend of the two amputees.*

These colours identify the amputees in the next tables and graphs.

In the SB condition the mean RR (Figure 90) of amputee #1 was 6,3 ± 2 breaths/minute and of amputee #2 4,94 ± 2,5 breaths/minute. In the NB condition, the amputee #1 had an average RR of 11,31 ± 2,5 breaths/minute whilst the amputee #2 of 13,19 ± 3,02 breaths/minute. In the SB condition where the target RR was of 6 breaths/minute the amputee #1 was able to maintain a quite perfect average RR, whilst the amputee #2 had a lower mean RR. In the NB condition where the target RR was of 14 breaths/minute amputee #1 had a lower average RR, while the mean RR of amputee #2 was quite closer.

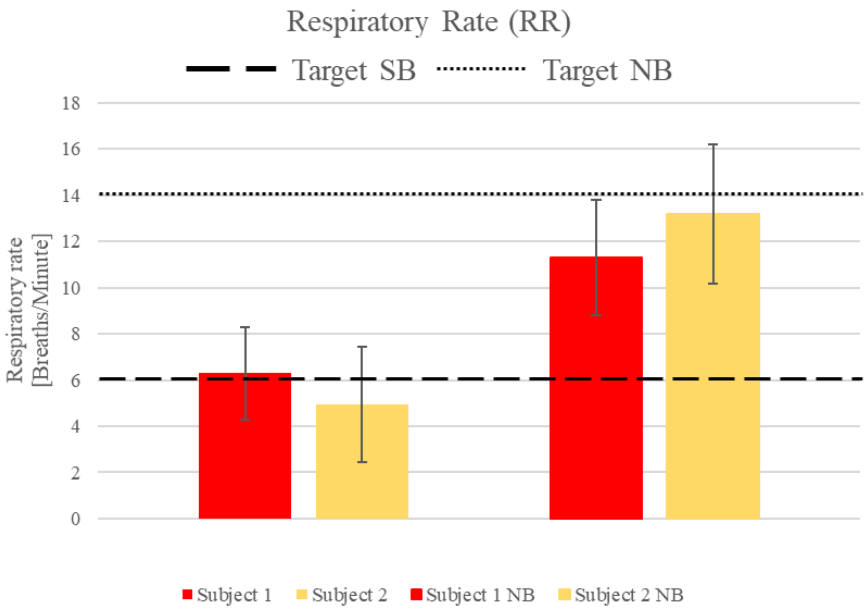


Figure 90: *Average Respiratory Rate based on condition, with standard deviation.*

The success rate (Figure 91) in the SB condition was of 50% and 75% for amputee #1 and #2 respectively (8 and 12 successful trials over 16), while for the NB condition the success rate achieved was 93,75% and 68,75% (15 and 11 accomplished trials over 16). In the NB condition the average success rates was definitely high for amputee #1, who only failed once.

Amputee #2 had more difficult to succeed the task in the NB condition with respect to amputee #1 but performed better in the SB condition, where amputee #1 succeeded only half of the time.

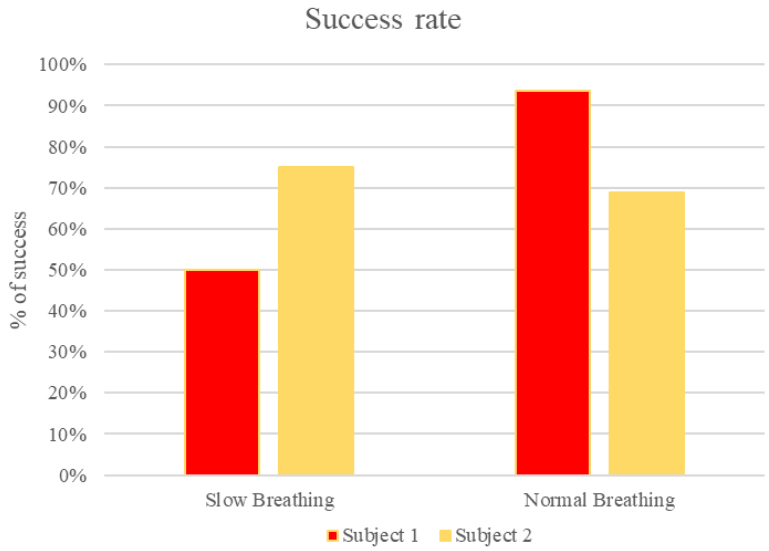


Figure 91: *Success rate of the 16 experimental trials based on condition.*

Each score of the subjective questionnaire is reported in Table 18 based on condition (Slow Breathing and Normal Breathing) and amputee (#1 and #2). The two amputees on average assigned higher scores with respect to the ones given by the healthy subjects. In fact, differently from these latter, the two amputees' scores often surpassed the middle score (3) of the 5-point Likert-type scale. Amputee #1 assigned higher scores to the SB condition in the "body ownership" scales (scale 2, 3 and 4), whilst amputee #2 gave almost the same scores in both conditions.

Scale type	N	Questionnaire Items	Slow Breathing		Normal Breathing	
			#1	#2	#1	#2
Experience	1	After this session I feel quite stressed	1	2	1	2
Body ownership	2	I felt as if I was looking at my hand	4	3	4	3
	3	I felt as if the virtual hand was part of my body	5	2	4	3
	4	It felt as if the contact I experienced was directly caused by the sphere that was approaching the virtual hand	5	4	3	4
Control	5	It felt as if I had more than one right hand	1	1	2	1
	6	I felt as if my hand was turning virtual	5	1	3	1
	7	I felt as if I could move the virtual hand	3	2	2	3
	8	It felt as if the contact I experienced came from somewhere between my limb and the virtual hand	1	2	1	4
Body Disownership	9	It seemed as if my hand had disappeared	1	1	5	2
	10	It seemed as if I could not really tell where my hand was	1	1	1	3
	11	It seemed as if I was unable to move my limb	5	3	5	2
Experience	12	I felt emotionally involved in the situation	4	3	4	3
	13	I perceived intensely my bodily sensations	5	3	5	3
	14	I felt the relation between my breath and my virtual hand	5	3	5	3

Table 18: *Post-session subjective questionnaire.*

The time estimation (Figure 92) in the SB condition was of 10 minutes for the amputee #1 and of 15 minutes for the amputee #2. In the NB condition the time estimation was instead equal to 5 minutes for amputee #1 and 10 minutes for amputee #2. Hence, as for the healthy subjects, the time estimation of the experimental session was lower for both amputees in both conditions compared to the real duration. Precisely, the estimations for both amputees were lower in the NB condition compared to the SB one.

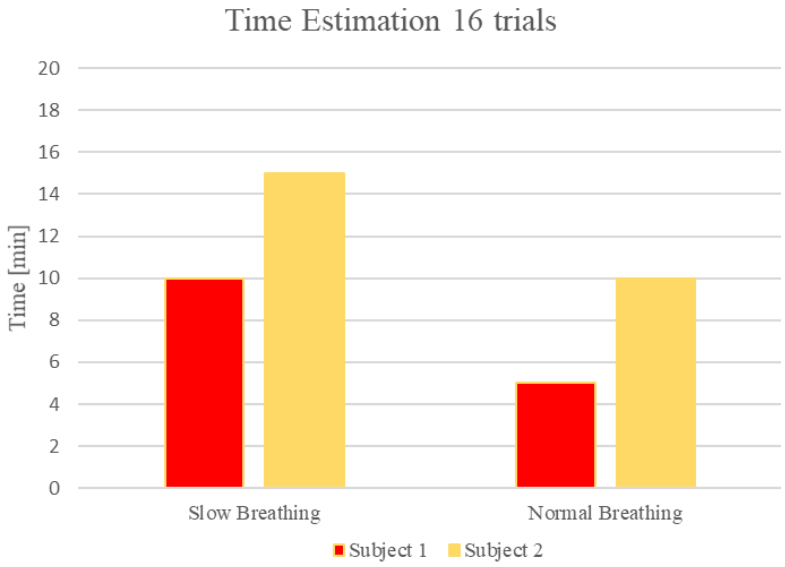


Figure 92: *Time estimation of the 16 experimental trials based on condition.*

The proprioceptive drift (Figure 93) tended in each condition and for both the amputees towards left. The proprioceptive drift for the SB condition was of 3 cm towards left for the amputee #1 and 4,7 cm towards left for the amputee #2. In the NB condition for the amputee #1 the measured drift was again of 3 cm towards left whilst for the amputee #2 it was equal to 2,5 cm towards left. Hence, for amputee #1 the lateral drift was the same in both conditions whilst for amputee #2 the drift was higher in the SB condition, in contrast with his time estimation.

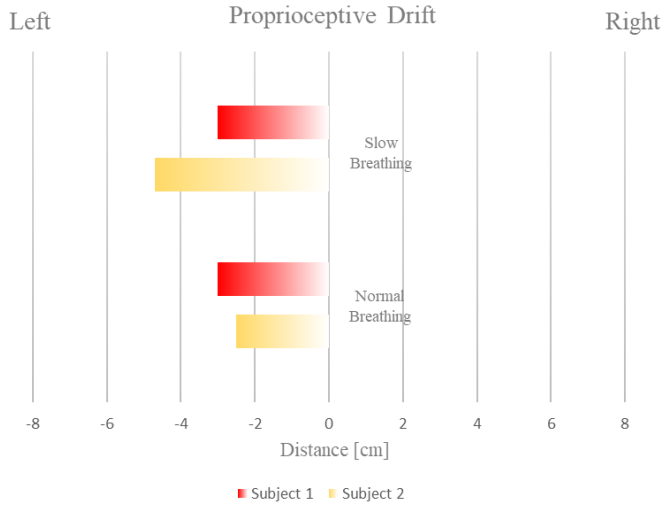


Figure 93: *Proprioceptive drift based on condition.*

4 Discussion

In the following Chapter, the results presented in Chapter 3: Results are discussed. As for the Materials and methods and Chapter 3: Results, this Chapter is divided into two sections regarding, respectively, the pre-validation of the post-market clinical trial and the feasibility study on the embodiment stimulation.

4.1 Pre-validation of the post market clinical trial

The discussion of the results of the pre-validation is divided into three subchapters related to the three main aspects under investigation: the user experience, the embodiment and the functionality.

4.1.1 User experience

The raw NASA-TLX questionnaire investigates the workload perceived during the functional tests. The more an amputee uses his prosthesis the more he acquires confidence and experience, feeling the workload more soft. For this reason, a decreased total score means an improvement. The increase at the beginning of the study (Figure 69) with *Hannes* (T2), compared to the commonly used prosthesis (TB), can be considered normal since the users did not have familiarity with the new prosthetic device. In general, the descending trends of Figure 69 confirms the improvement of the raw NASA-TLX questionnaire over time. Hence, the results of T4 demonstrate that *Hannes* provided a better UX in comparison with the users' common prosthesis evaluated in TB.

The SUS questionnaire investigates the usability of the device, with higher score indicating higher usability. The ascending trends appreciable in Figure 70 thus demonstrate the subjects' improvement. The results are since the beginning higher than the threshold of 68%, the minimum value to overcome in order to consider a system usable. At T4 the results of each subject are much higher than the threshold, meaning that the subjects consider *Hannes* a very usable prosthetic system. In conclusion, as it can be seen in T4 with respect to TB, each subject considers *Hannes* more usable than their previous commercial prostheses.

The TAPES questionnaire evaluates the general UX in daily activities, with higher results indicating a better UX achieved. The positive trends of Figure 71 confirm the improvement of the UX related to *Hannes*. Furthermore, comparing T4 with TB, Subject 1 and 3 demonstrate an appreciation in favour of *Hannes,* while Subject 2 manifests to equally appreciate both the reference hand and *Hannes*.

The Ad hoc questionnaire shown in Table 11 explores UX and embodiment aspects of the daily life in relation with the prosthesis' usage. For instance, it investigates if the fingers' movement is considered natural, if the device improved the autonomy, if the thumb or the wrist needed to be often adjusted. The overall improvement for each subject from TB to T4 demonstrate an increasing appreciation for *Hannes*. Furthermore, from T2, the absence of blank-left items means that *Hannes* provides features that the commonly used prostheses did not have. All subjects improved the feeling of the prosthesis' ownership over time as manifested in item 15 which indeed shows an increased embodiment. Subject 1 and 3 totally agreed with the item 22 indirectly exploring if *Hannes* prosthesis is better than the commonly used prostheses while, the score of subject 2 shows that, in his opinion, *Hannes* is as preferable as his reference hand. The subjects found very appreciable the naturalness of the device's movements, the possibility to adjust the thumb and the wrist (also in the "free swing mode"). *Hannes* assured the users autonomy, successes in bi-manual tasks and an intuitive control.

4.1.2 Embodiment

The RHI questionnaire reported in Table 12 is the second questionnaire used to evaluate the embodiment process after the Ad hoc questionnaire already discussed above. This questionnaire was administered after a session of the modified Rubber Hand Illusion (explained in chapter 2.2.1.2.2: Embodiment) and aimed at investigating the paradigm just experienced. Having regards to the positive assigned scores, it can be said that Subject 3 demonstrated the highest embodiment level.. Subject 3, in T4, assigned the only non-maximum score in item 8, but with the explanation that he felt the contact coming from the prosthesis itself and not in a undefined middle point. Based on their scores, it can be stated that subjects 1 and 2 were less suggestible. Nevertheless, subject 1 shows a little improvement over time demonstrating to stronger feel the effects of this paradigm. Subject 2 instead became more and more sceptical and quite annoyed. By the subjects' feedbacks, the conditions in which the paradigm took place (i.e. light, noise, surrounding confusion) influenced the experience, as well as the aspect of the prosthesis (a skin coloured glove was found to be more stimulating). It can be said that this paradigm can be effective in certain conditions and with subjects open to this kind of experiences.

The proprioceptive tasks evaluated the capability of the subjects to correctly perceive the peripersonal space and the presence of the prosthesis. The goal of these tasks was the identification of specific points of the sounded arm with the prosthesis and of the prosthesis

with the contralateral arm. The joining of the hands in three different positions (under, at the level and above the shoulders) was the last requested goal. A correct execution is manifested by deviations equal to 0. The overestimations of the distances observed in subject 1 indicate that in this subject's corporal mental scheme the prosthesis was longer than in reality (Table 13). The improvements over time towards the 0 deviation show that the constant usage of the prosthesis during the three-month period brought to a better integration of *Hannes* into the corporal mental scheme, demonstrating an increase in the embodiment of this prosthetic hand. Subject 2 and 3 tended to underestimate the space occupied by the prosthesis, showing again an incorrect integration within the body scheme (Table 13). Both subjects, as subject 1, improved their peripersonal space's perception over time, hence exhibiting a stronger embodiment. It can be said that subject 3 was the subject who better integrated the prosthesis, successfully accomplishing each task in the last session (T4). The mono-manual task relating to the elbow could present better results with the contralateral hand because the subjects were able to identify the elbow with the connection of the socket. Correctly perform the bi-manual tasks was found easier probably because of the involvement of the remaining limb, which could have given a reference to the other sounded arm. All subjects achieved better results (obtaining smaller deviations) with *Hannes* in T4 with respect to their commonly used prostheses evaluated in TB, showing an improved embodiment. It can be then concluded that the proprioceptive tasks were valid methods to investigate the embodiment in an objective way, demonstrating that *Hannes* hand was better embodied after the three-month study than the previous prostheses.

The postural balance test aimed to verify the level of embodiment achieved through the sways of the body. The assumption is that the more a prosthesis is embodied and integrated in the corporal scheme, the lower the oscillations of the body are. Having regards to the oscillations reported in Table 14 and shown in Figure 76, Figure 77 and Figure 78, the subjects generally reduced their sways with *Hannes* over time, showing the positive evolution of the embodiment process influenced by the passing of time. Furthermore, the improved performances with *Hannes* in T4, compared to the one with the commercial hands, demonstrate a greater embodiment with the novel prosthesis for each subject. The big difference in the results of subject 3 with respect to the other two participants may be explained by the big difference in age. It has been demonstrated that elderly people have greater body sway [71]. Indeed, subject 3 was 66 years old whilst subject 1 and 2 was almost half his age (31 and 33 respectively). Moreover, also the higher sways in the Eyes-Closed

condition for each subject are proved to be normal since a greater stability is obtained when vision is allowed [72], [73]. The several deteriorations of subject 1 and 2 between the results obtained in T4 with *Hannes* and the ones obtained without any prosthesis demonstrate that the presence of the prosthesis disturbs the body balance, hence the prosthesis is not as much integrated in the mental corporal scheme as the stump and the remaining limb. In fact these subjects seem to be more stable without any external device. Only subject 3 seems to be more stable with the prosthesis, maybe because the traumatic event took place more than 50 years ago and he is definitely more used to wear an external tool. In conclusion, the postural balance test can be defined as a good objective method to evaluate the embodiment. A further analysis could introduce the investigation of anticipatory postural adjustments, which could give other objective measures for the evaluation of the embodiment.

4.1.3 Functionality

The reduction of each subject in the MMDT-P's times over the acquisitions with *Hannes* (highlighted in Table 15 and Figure 79) demonstrate that the prosthetic usage over time improves the functionality. The synergistic movement of the digits of *Hannes* and its velocity permitted to perform the task faster than Bebionic and Variplus hands for subject 1 and 2, showing the high potential of this novel prosthesis. Only subject 3 performed better with Michelangelo, revealing how this commercial prosthesis could offer a better functionality.

The same conclusions can be drawn looking at the results obtained with the SHAP test (Table 15). The usage over time allowed the subjects to better control *Hannes*. Subject 1 and 2 only had worse performances with the lateral and tip grasps. This could mean that *Hannes* does not offer great executions with these two grasps compared to Bebionic and Variplus. Subject 3 instead had problems with the tripod and extension prehensile grasps, indicating that Michelangelo works better for tasks which imply these grasps while *Hannes* shows deficiencies. These results could be a useful feedback for the engineers working on the *Hannes* hand. However, these problems could be also related to the fact that *Hannes* offers an adaptive grasp. Apparently, this feature could give the sensation of a less firm grasp compared to the mechanical grasp offered by the commercial hands like Bebionic, Michelangelo and Variplus. In reality, this could just be a matter of habit. Anyway these results should be deeply investigated for a better evaluation and could be a useful feedback for the engineers working on the *Hannes* hand. The Index of Functionality of the SHAP test

(Figure 80) demonstrates that overall *Hannes* offers better functionalities than the commercial prostheses.

Finally, the same conclusion is demonstrated with the BBT test (Table 15 and Figure 81). Again, it is confirmed the improvement over time. Moreover, when using *Hannes* the subjects were able to transfer more cubes than with their previous prostheses. This better performance can be attributed to the high velocity in the opening and closing which *Hannes* offers, together with the fine motor control which allows to grasp very small objects with a precise grasp.

Considering the results obtained in the functional questionnaires (QuickDASH and OPUS-UEFS), highlighted in Table 16, *Hannes* was considered to facilitate the daily tasks.

The QuickDASH scores were supposed to decrease towards the 0, which means absence of disability. In Figure 82 the decreasing trends over time confirm the improvement and show how the increasing usage of the prosthesis over time helped in the accomplishment of functional activities. At the end of the study (T4), each score was better than in TB and almost equal to 0, demonstrating that *Hannes* improved the functionality exploited in the ADLs, allowing better performances than with the commercial prostheses.

Final improvements also regard the OPUS-UEFS scores (Figure 83). Subject 1 and subject 2 declared to use the prosthesis in an increasing number of situations over time. However, the increase of the usage corresponds to the decrease of the quality of these situations, reported as the goodness of the score. Hence, the subjects included the prosthesis in more daily tasks, but the resulting effect was not so admirable. Actually, the involvement of the prosthesis, even if it leads to worse performances, demonstrate that the subjects act with both hands, showing a high level of embodiment. Furthermore, the low quality offered by the prosthesis could be justified by the fact that the subjects always pretend more by the prosthesis, again showing a high consideration of it. Only subject 3 reduced the prosthesis involvement over time but increased the quality of the activities, maybe implementing a different strategy: less but better. In general, the functional questionnaires demonstrate that *Hannes*, after only a three-month period, offers a better functionality in daily activities compared to the commercial prostheses.

4.2 Embodiment stimulation – pilot study

The discussion of the feasibility pilot study's results on the embodiment stimulation is separately made for the 12 healthy subjects and the 2 amputees who participated to the study.

4.2.1 Healthy subjects

Figure 85 showed how properly the participants on average followed the different instructions for both conditions. The two mean Respiratory Rates demonstrate that the requested frequencies were accessible and well distinguished in both conditions (the difference between the Respiratory Rates in the two conditions was found to be significant with $p<0,001$). The standard deviation of both conditions decreases over the trials because there is a learning effect of the right respiratory rate to maintain. It was noticed that the subjects' performance in terms of successful trials was quite variable across the trials, highlighting how maintaining an appropriate RR to trigger the vibration can become complex to manage. These observations suggest the need of a task re-design for facilitating the execution of the biofeedback training. Having regards to the results, it can be said that the task under the NB condition was slightly easier for the subjects to accomplish.

The two aspects investigated by the scales 3 and 4, which gave significant differences between the two conditions in favour of the SB one, are directly connected to the embodiment process. Thus, it can be concluded that the Slow Breathing condition made the subjects feel stronger the extension of their body into the virtual environment (through the virtual hand), enhancing a stronger embodiment of the virtual hand.

The participants on average underestimated the duration of the 16 experimental trials in each condition. This could suggest that in both conditions, especially in the SB one as predicted since this condition's estimation was the lowest, the subjects were really focused on the task and immersed in the spatially augmented reality, conditions that are supposed to facilitate the embodiment.

Finally, the breathing condition was found to significantly affect the proprioceptive drift, measured at the end of the experiment. The 12 subjects in the SB condition averagely replaced the smartphone towards left, and so towards the monitor and the virtual hand showing high embodiment, whilst in the NB condition the average drift was towards right, far the monitor and the virtual hand showing low embodiment. These results indicate that the SB condition improved the ownership, and hence the embodiment process. The

proprioceptive drift can be considered as an objective measure of embodiment since it depends on an unconscious action made by the subjects.

Having regards to the obtained results, it can be confirmed that the experiment was accessible and the initial assumptions verified. Indeed, it can be said that the Slow Breathing rate influenced more the embodiment process of the virtual hand with respect to the Normal one.

4.2.2 Amputees

As obtained with the healthy subjects the four mean RR in general demonstrate that the requested frequencies were accessible and well distinguished for both the amputees in both conditions. The task in the NB condition was found to be easier for amputee #1, who just failed one trial. Amputee #2 instead performed better under the SB condition. Again these results suggest the necessity to facilitate the execution of the biofeedback training.

Regarding the post-session adapted questionnaire the higher scores assigned by the amputees with respect to the healthy subjects show a higher involvement. It can be supposed that this greater immersion and susceptibility can depend on their physical condition. The absence of a limb could help the integration of a replacement, even if virtual. Based on the given scores, amputee #1 exhibits an unconscious preference for the SB condition, while the scores of amputee #2 do not evidence a better "embodiment stimulation" condition.

As for the healthy subjects the time estimation of the experimental session was lower for both amputees in both conditions compared to the real duration. This result again is seen as a consequence of high levels of concentration and immersivity maintained by the amputees during the experiment, conditions supposed to facilitate the embodiment. Differently from what expected, for both amputees the estimation was lower in the NB condition than in the SB one.

Finally, the proprioceptive drift was towards left, the monitor and the virtual hand, in both conditions and for both the amputees, again showing the high involvement already cited and hence the embodiment's effects.

The experiment was accessible also to the prosthesis' users. Considering the different results given by the questionnaire, the time estimation and the proprioceptive drift by the two amputees it cannot be said that one condition was able to better stimulate the embodiment with respect to the other one. It must be specified that just two subjects are a too small sample

size to reach valid and consistent conclusions. The involvement of amputees in this pilot study was purely exploratory and was actuated to check the feasibility and availability of these latter. Based on the obtained results and feedbacks, it can be said that these two goals were accomplished.

5 Conclusion

The pre-validation of the post-market clinical study on *Hannes* hand verified the feasibility of the clinical protocol and the effects given by the prolonged use (three-month period) of *Hannes*. The primary objectives of this study were the *improvement* (through the daily use) of the **user experience** and the **embodiment** of *Hannes* hand, and the *evaluation* of these possible improvements over time. Furthermore, the secondary goal regarded the evaluation of the **functionality** offered by *Hannes*.

The results obtained during the pre-validation are very satisfying under several aspects: they indeed validated the methodology and verified that everything was applicable, also in term of time. The questionnaires provided validated methods to investigate the subjects' feedbacks. The validated functional tests, instead, provided an objective evaluation of the functionalities of *Hannes*. Nevertheless, the tests and methods (proprioceptive tasks, postural balance test, modified RHI) used to evaluate and stimulate the embodiment have proved to be a valid form to investigate and enforce the level of integration (embodiment) of a prosthesis in a prosthesis user.

Accomplished results can be considered positive because a general improvement is appreciable in all the investigated areas. These improvements, observed during the course of the pre-validation, demonstrate that the usage of *Hannes* hand over time improved the UX, the embodiment and the efficacy of the functionality perceived by the subjects. As highlighted by the excellent results accomplished at the end of the study, *Hannes* can be considered a valid and maybe even a better option to the commercial prostheses.

The subjects declared their appreciation towards this novel prosthetic hand, stating their preference in favour of *Hannes* with respect to their commonly used prostheses. They found the device easy to use, simple and efficient, giving positive outcome related to their experience with the prosthesis. The high efficacy in terms of functionality offered by *Hannes*, confirmed by the great results in the functional questionnaires and tests, were really appreciated by the subjects. The daily usage over the three-month period proved to increase the subjects' capacity in controlling the prosthesis, leading to an excellent dexterity and to a good accomplishment of the ADLs. If a prosthesis user feels satisfied with the functionality of his prosthesis he uses it more, promoting the integration of the device. When using *Hannes*, the subjects also stated to feel themselves less impaired and more independent. All these conditions related to the UX and functionality can lead to the strengthening and

improvement of the embodiment. In conclusion, it can be said that *Hannes* with its naturalness and the related positive aspects already discussed improved the embodiment feeling of the subjects, allowing them to perceive the prosthesis as part of their body rather than an external tool.

The presented results of the pre-validation constitute the starting point of the official clinical trial, where 15 participants new to *Hannes* system should be included. With only three subjects involved in this preliminary trial, already familiar with the device, it is not possible to certainly declare that all the initial goals are definitely accomplished, but the conditions are promising. Furthermore, it should be remembered that some components of the official clinical trial, such as the initial training or the Robotic Hand Illusion, were missing because of time-related and covid-related problems. These latter could be indeed an added-value. Moreover, the right execution of the official clinical trial would improve the authenticity and reliability of the study.

Hence, having regards to the results, it can be concluded that the clinical protocol carried out in this pre-validation could offer a valid strategy for the evaluation and improvement of the user experience, the functionality and most of all the embodiment of an upper limb prosthesis. All these aspects concerning the human-machine interaction should be considered as fundamental to assure the prosthesis acceptance and should be taken into account from the beginning of the rehabilitation process.

For what concerns the feasibility pilot study on the embodiment stimulation, it aimed to verify if a *self-modulation* of the psychophysiological state through the *respiratory rate* can induce a *strengthening effect* in the **embodiment** of a virtual hand. In particular, the study explored if a *slow breathing rate* provides better results compared to a normal one. Moreover, the further goal was to explore the feasibility of this system for an at-home embodiment training for amputees and their prostheses.

It can be said that, having regards to the results, the SARB setup designed for this study was able to correctly detect the subjects' breathing, process the respiratory rate and give the programmed feedback to the participants. The spatially augmented reality was developed with the idea of an at-home usable system, so it is far from the immersive setting used in the usual VHI studies. Nevertheless, the embodiment evaluation through the questionnaire and the proprioceptive drift showed good results, precisely in favour of the SB condition. The initial assumptions can be then confirmed. Furthermore, the amputees' feedback affirmed

that this tool could be a valid at-home “embodiment training” for their prostheses, demonstrating the potential of the custom-made system.

Future goals comprise the inclusion of more participants to reach more consistent results, the improvement of the setup’s robustness in term of breathing’s detection and further analysis on the possible correlation between the success rate and the embodiment process. Moreover, the integration of the subjects’ real-time participation, for example with the opening and closure of the virtual hand, could also stimulate the agency component of the embodiment, further enhancing this process. This tool could be exploited for the embodiment training of other prostheses by simply changing the virtual aspect of the virtual limb.

The proposed **pre-validation** and **“embodiment training”** can be finally considered valid approaches to help prosthesis users to better embrace their condition and to properly take advantage of their missing limb’s replacement, the prosthesis. What has been proposed in the two studies could be performed with any other prosthesis. Hence, the advantages led by this thesis are universal.

6 Bibliography

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