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Dissemination Level		
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PP	Restricted to other programme participants (including the Commission Service)	
RE	Restricted to a group specified by the consortium (including the Commission Service)	
CO	Confidential, only for members of the consortium (including the Commission Service)	

Document History

Version	Date	Author	Summary of Main Changes
1	29/11/2012	M. Niccolini, S. Tognarelli (SSSA)	First version of the document
2	30/11/2012	M. Niccolini, S. Tognarelli (SSSA) and M. Carbone (UNIPI)	Refinement
3	03/12/2012	Arianna Menciassi (SSSA)	Revision of the document
3	03/12/2012	Paolo Dario (SSSA)	Approval of the document and submission

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Executive summary

This document presents the medical assessment of the ARAKNES clinical platform.

As regards the research platform, whose development is less advanced, the assessment was done only on animals (see D10.5).

This document illustrates tests performed at the Cisanello Hospital in Pisa mainly with expert users (first phase) and subjects with no prior experience (second phase), as also suggested by reviewers.

1 Experimental assessment of the ARAKNES clinical platform: first phase

A preliminary evaluation of the SPRINT robot has been performed in September 2011 with the SPRINT 1.0 prototype and a home-made master console (Figure 1).

The bimanual prototype has been used by five experienced surgeons for pick and place exercises and for intracorporeal suturing in a trainer box assembly. These exercises were designed to assess the feasibility of the overall system, as well as to verify the dexterity of the two arms in a master-slave teleoperated configuration. Surgeons performed the exercises watching the test-bed scene on the 3D display wearing polarized glasses (Figure 1).

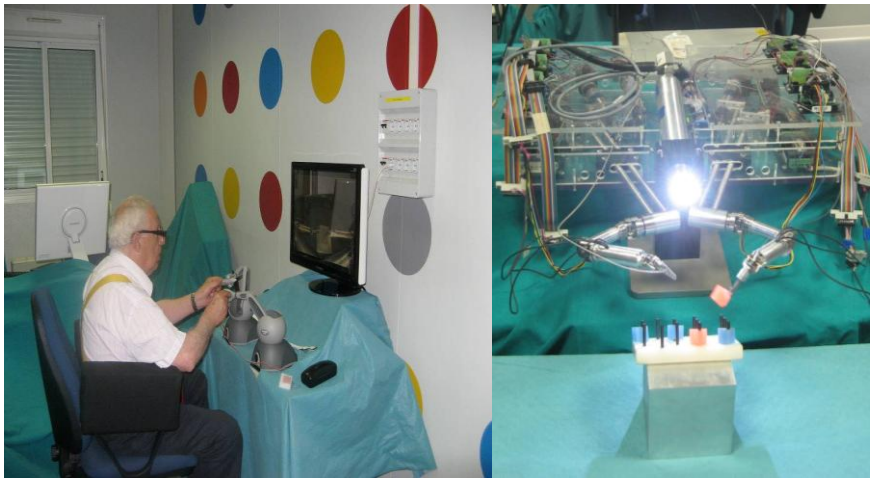

Figure 1: Surgeon at the console side during a test (Left); SPRINT 1.0 prototype (Right).

The first exercise consisted in a peg-transfer setup that reproduces the first task of the SAGES Fundamentals of Laparoscopy manual skills (FLS) tests. The task requires the operator to pick-up a peg with one robotic arm, transfer it to the other arm, and then place it to the other side of the pegboard respecting the number on the peg holder (Figure 2). The exercise was considered full-finished once all the pegs were transferred, successfully or not, from right to left and vice versa.

Another goal of this test was to estimate the learning curve associated to the use of the robot. Therefore, the time spent for each peg transfer was recorded, and the test carried out by each surgeon was repeated two times. Since pegboard housed 6 pegs, the total amount of pegs transferred, after moving twice (from right to left and from left to right) was 24. For each surgeon this test was the first experience with the SPRINT robot and they did not have any familiarization runs on the system before the tests.

The second test required the surgeon to perform suturing with intracorporeal knots (Figure 2). In this case the time needed to tie one knot has been recorded for comparison purposes.

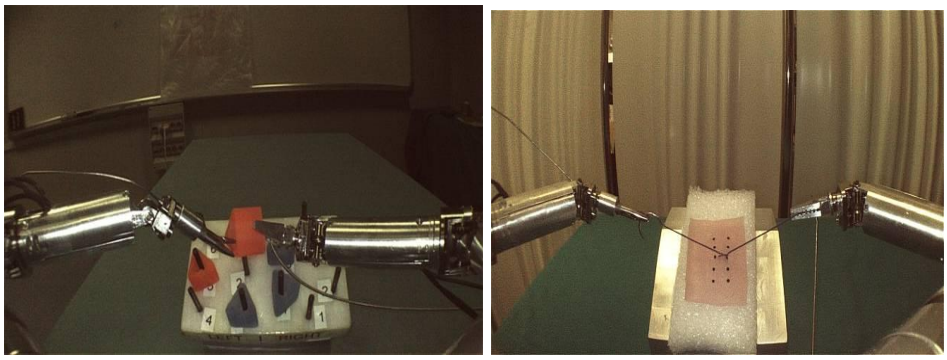

Figure 2 : Pick and place exercise (Left) and suturing exercise (Right).

All but one of the participating surgeons have at least 20 years of surgical experience. Only one surgeon has no prior experience in Single Port Laparoscopic Surgery (SPLS), and all were familiar with robotic-assisted laparoscopy using the daVinci system. The full details of the surgeons participating in the assessment are shown in Table 1.

Table 1: Details of participating surgeons.

Surgeon Background	**1**	**2**	**3**	**4**	**5**
Age	46	49	37	51	47
Specialization	General surgery	Urology	General surgery	General surgery	Gynecology
Years of experience	21	20	12	25	20
Experience with robotic assisted laparoscopy	YES	YES	YES	YES	YES
Experience with SPL	YES	NO	YES	YES	YES

Figure 3 and Figure 4 show the learning curve associated with the SPRINT 1.0 robot from two different viewpoints. In the first case (Figure 3), the time spent for transferring each peg has been averaged over all the surgeons and plotted with respect to the number of pegs. Figure 4 describes the percentage of error averaged by all the surgeons, computed as the number of pegs lost divided by the total amount of pegs picked up and plotted with respect to the number of pegs. Both the curves start to decrease significantly after a few peg transfers. The mean time needed to transfer one peg decreased approximately by 50% after 7 pegs: from 97 seconds spent for the second peg to 50 seconds for the transfer of the seventh peg. Thereafter, the slope of the curve continues to decrease reaching a value of 31 seconds after 17 transfers. As it can be seen in Figure 4, the percentage of error rate starts from an initial value of about 50% and diminishes by half after 15 pegs.

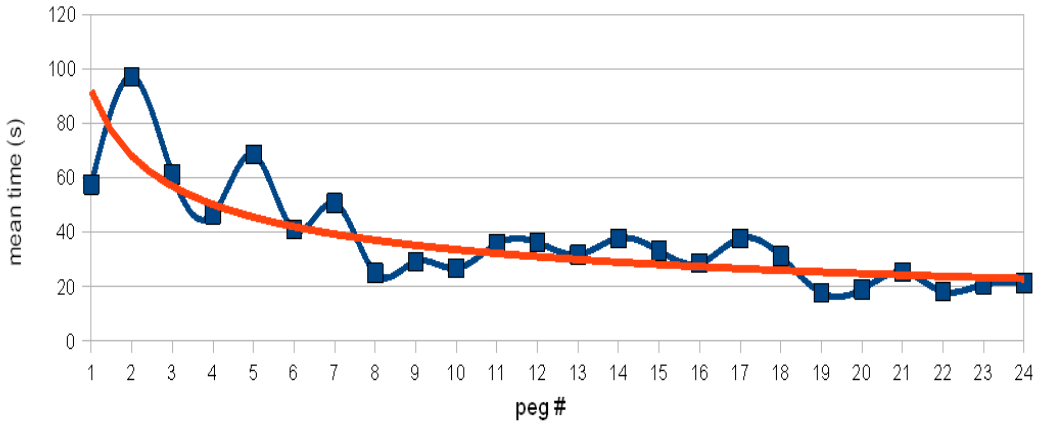

Figure 3: Peg mean time transfer.

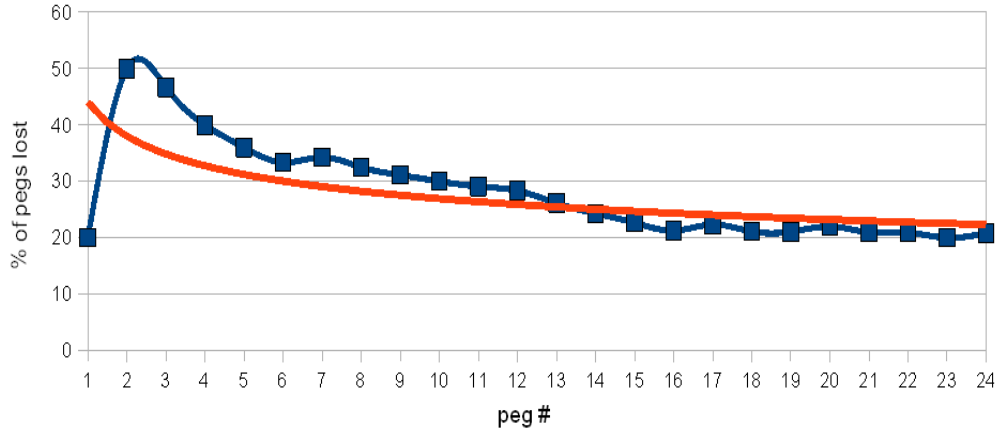

Figure 4: Percentage of error in peg transfer.

Although surgeons had no familiarization runs before the tests, both the curves show that surgeons start to become familiar with the robot already after 9 minutes of use. Moreover, the trend of the regression curves indicates that the plateau has not been reached yet, thus implying that current results are likely to improve further after more practice.

In the second test, surgeons were required to perform an intracorporeal suture (surgeon's knot). The suture was completed by all the surgeons. Maybe due to the lack of experience in the field of SPLS, one surgeon required 796 seconds to complete the task, while the other surgeons completed the suture in less than 314 seconds or less (Figure 5).

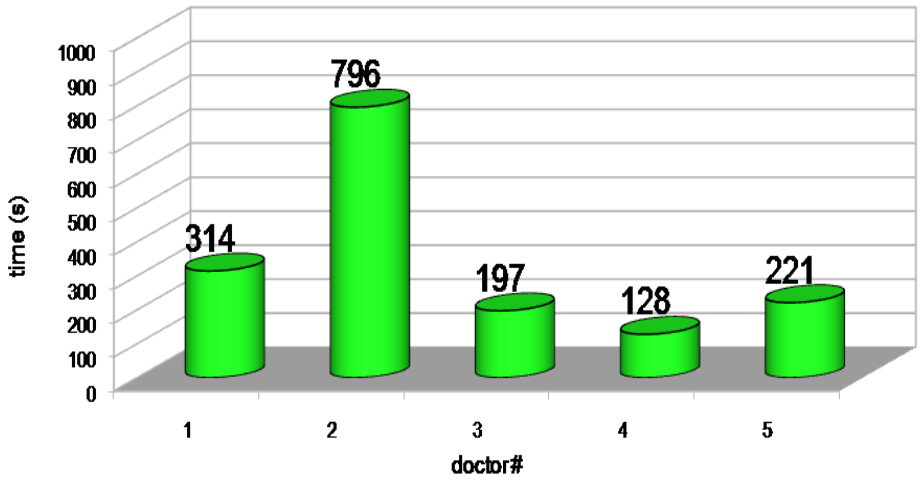

Figure 5: Suturing time.

2 Experimental assessment of the ARAKNES clinical platform: second phase

New laboratory tests have been performed with the current SPRINT 2.0 prototype and the ICL console by non experienced surgeons, (Figure 6).

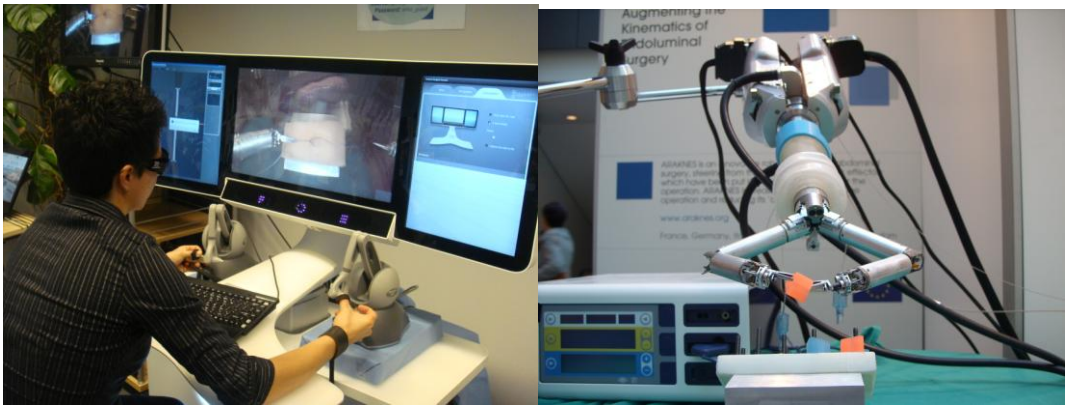

Figure 6: ICL Console (Left) and SPRINT 2.0 (Right).

Differently from the previous tests session, almost all the subjects had no prior experience with robotic assisted laparoscopy nor with single port laparoscopy.

The details of each subject are summarized in Table 2, while Figure 7 shows the distribution of their specialization.

Table 2: Details of participating surgeons.

Test number	Age	Specialization	Number of years of experience	Number of operations performed as first surgeon	Experience with Robotic-Assisted laparoscopic surgery	Experience in single port laparoscopy
T1	30	Vascular Surgery	4	0	N	N
T2	29	Vascular Surgery	2.5	0	N	N
T3	27	Thoracic surgery	1	4	N	N
T4	29	General Surgery	1.5	0	N	N
T5	32	Gynecology	3	15	N	N
T6	41	Vascular Surgery	10	>3000	N	Y
T7	55	Vascular Surgery	30	>4000	N	N
T8	29	Thoracic surgery	3	6	Y	N
T9	31	Gynecology	3	0	N	N
T10	36	General Surgery	2	1	N	N
T11	30	Gynecology	3	0	N	N
T12	29	General Surgery	1	0	N	N
T13	32	General Surgery	7	25	N	N
T14	30	General Surgery	5	12	N	N
T15	34	Orthopedist	9	130	N	N
T16	31	Orthopedist	5	70	N	N
T17	30	General Surgery	5	1	N	N
T18	28	General Surgery	3	0	Y	N
T19	27	General Surgery	2	0	N	N

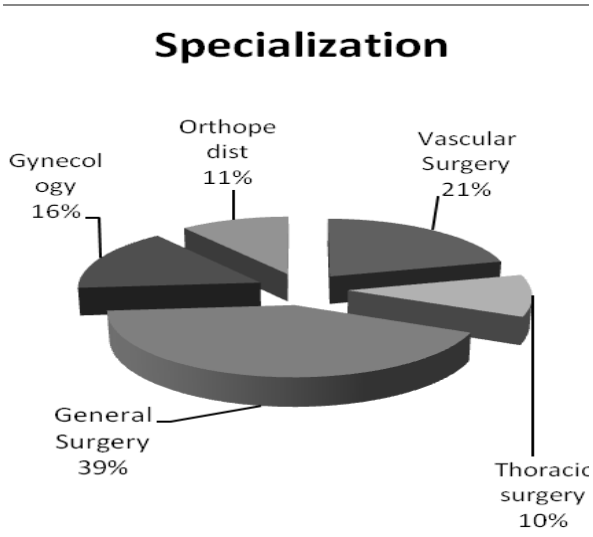

Figure 7: Percentage distribution of the specialization of the subjects

The subjects where asked to transfer the pegs first form left-to-right and then back from right-to-left. The time needed to perform each peg transfer was recorded, with a total of 12 transfer times for each subject. The mean time taken for each peg transfer is showed in Figure 8. The trend shows that there is a slight decrease of the mean peg transfer time when the pegs are transferred from right-to-left (peg numbers from 7 to 12).

The reason of this behaviour could be addressed to the right hand dominance of all the subjects. It is worth to note that the peg mean transfer time of the first 12 pegs is comparable to that performed by the five experienced surgeons of the previous test session. Also the percentage of pegs lost is slightly less than that of experienced surgeons even if strongly comparable (Figure 9).

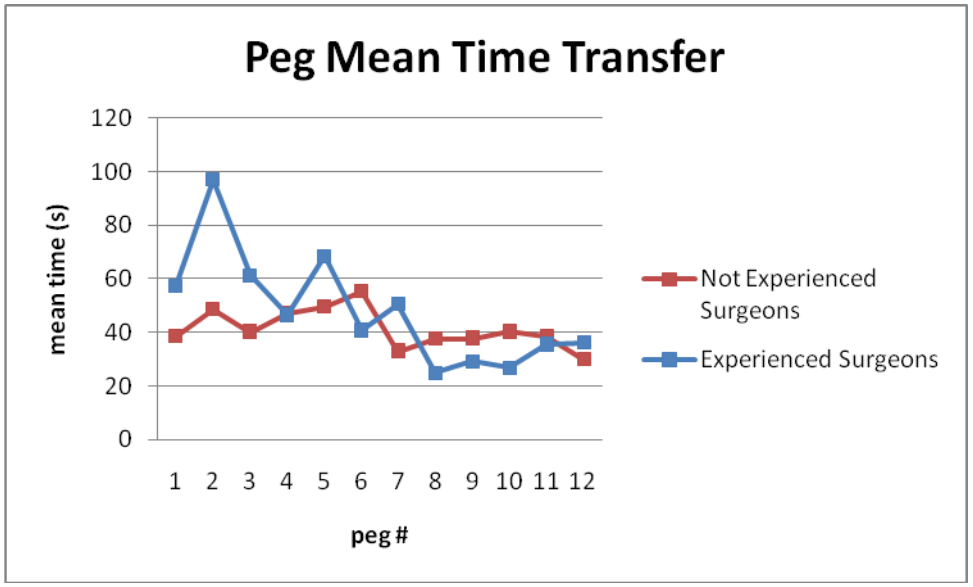

Figure 8: Peg Mean Transfer Time

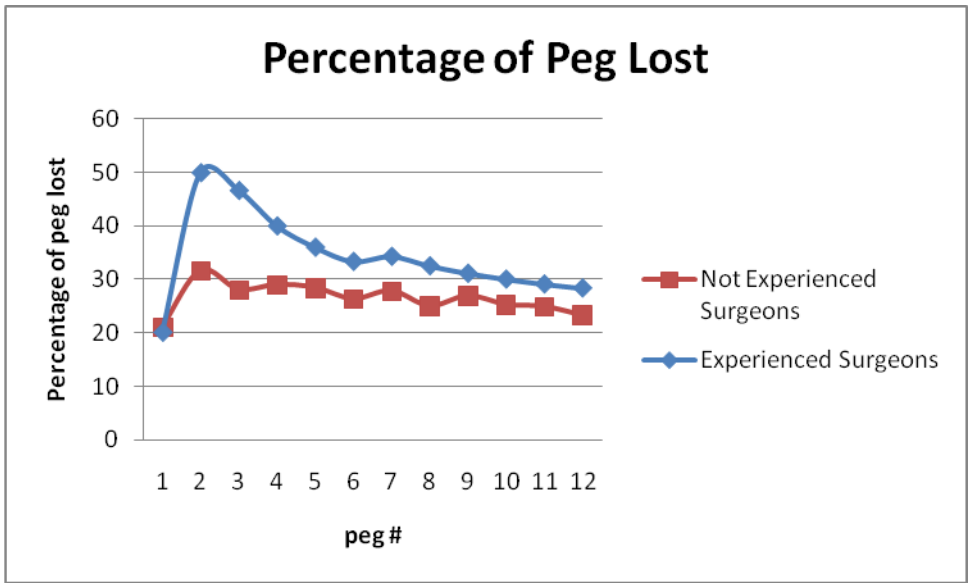

Figure 9: Percentage of Peg lost

Even if the suturing task has been completed by all the subjects of the table, a large difference between experienced and not experienced surgeons was oberved. The mean time to perform a surgical knot by an experienced surgeon using the SPRINT robot is about 331 s obtained from Figure 5, while a not experienced surgeon took about 670 s, that is two times larger. The causes of this gap could be addressed to:

- Lack of experience in teleoperated systems
- Slightly different kinematic of the robot (indeed experienced surgeons performed the tests with the SPRINT 1.0)

In order to exclude the second cause, one of the experienced surgeons that partecipated to the first test session has been asked to perform the test with the new platform. The measured performance, reported in Table 3, confirm that the main cause has to be addressed to the lack of training in robotic surgery of not experienced surgeons.

Table 3: Experienced Surgeon: test session 1 and 2.

	SPRINT 1.0	**SPRINT 2.0**
Peg Mean Time Transfer (s)	24.80	27.18
Percentage of Lost Pegs (%)	12.5	8.3
Suturing Time (s)	197	158

Finally, each subject was asked to fill a questionnaire for the qualitative evaluation of the different components/characteristics of the whole platform. A numeric scoring system from 0 to 10 was used to evaluate each item. The mean score obtained for each entry is showed in Figure 10.

Based on the standard deviation of each evaluated entry, we observed that each subject has a very personal judgment of the platform, especially for what concern the quality of the 3D viewing. On the other hand almost all the subjects agree in the judgment of intuitiveness, actuation by foot, available workspace, needle driving grasping force and ergonomicity of the console. More precisely the overall system has been judged to be comfortable, intuitive and with a large enough workspace. Contrary, the needle driving grasping force was judged not enough for a suturing task.

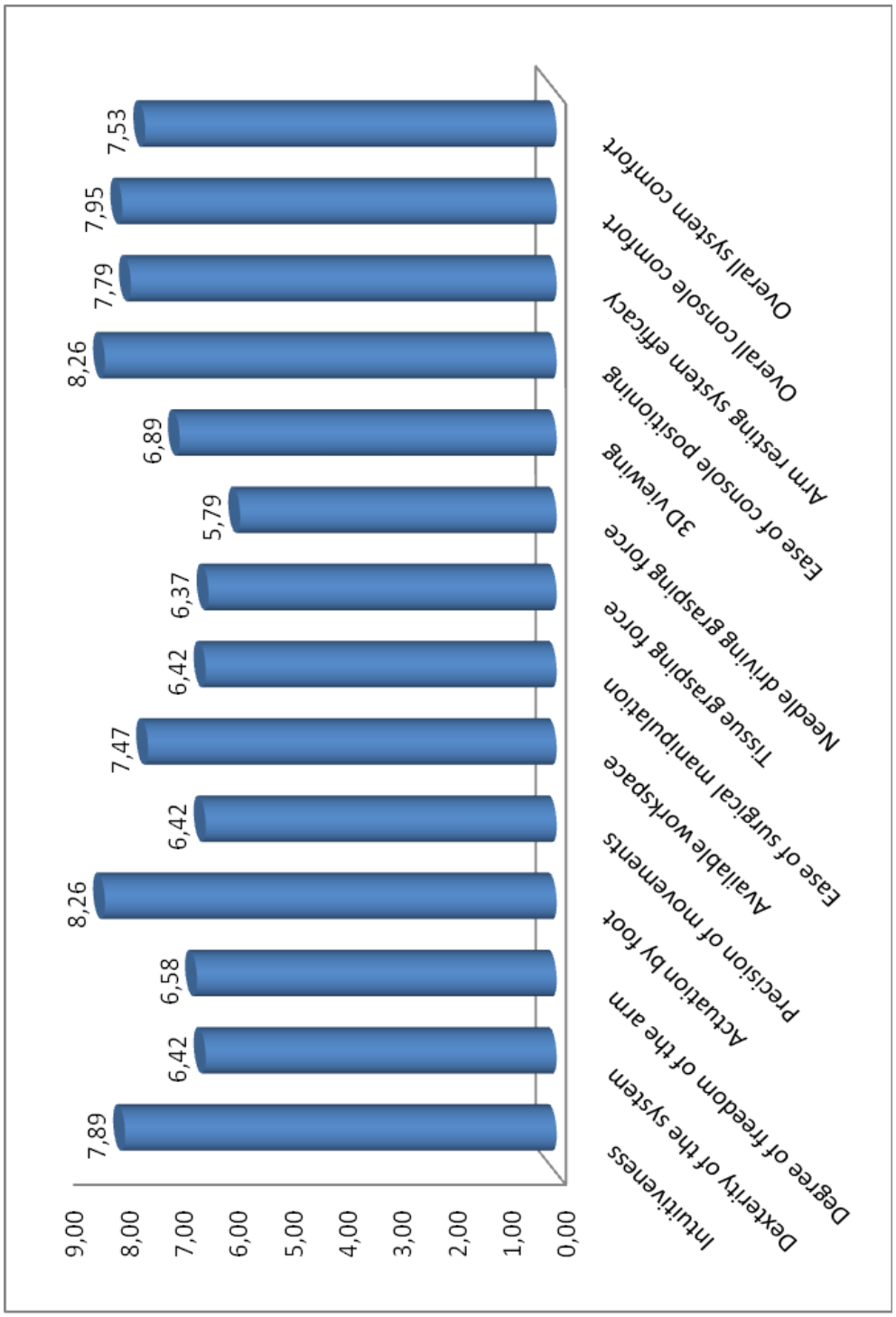

Figure 10: Questionnaire scores.

3 Conclusions

In conclusion, a protocol inspired by FLS tests has been followed. Pick and place and suturing tests have been completed with quite satisfactory results by all the surgeons, thus demonstrating the feasibility of the design and the overall usability of the system. As a matter of fact, the data from these tests indicate that despite not being allowed familiarizations runs, the surgeons involved became familiar with the use of the SPRINT robot exhibiting fast learning curves, thus confirming the intuitiveness of the system.