


Overview and perspectives about the robotic surgical certification process in Brazil: the new statement and a national web-survey

Visão geral e perspectivas sobre o processo de certificação em cirurgia robótica no Brasil: o novo regimento e uma pesquisa nacional online

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ABSTRACT

Objective: to appraise the general profile of the Brazilian robotic surgeon and the acknowledgment of the new certification process for robotic surgery upon the Associação Médica Brasileira (AMB - Brazilian Medical Association) statement. According to the AMB statement, medical societies and proctors have to achieve leading roles in training and certification of surgeons, acting in partnership with industry. **Methods:** a national web-based survey was promoted by the Colégio Brasileiro de Cirurgiões (CBC - Brazilian College of Surgeons) among their members. **Results:** the 294 answers were split into two groups: 133 (45.3%) who had robotic console certification, and 161 (54.8%) who did not have it. The overall median age was 46, but the non-robotic group presented more surgeons with at least 30 years of experience than to the robotic group (32.3% versus 23.3%, $p=0.033$). Surgeons with robotic certification more frequently work in a city with at least one million inhabitants than surgeons who were not certified (85.7 versus 63.4%, $p<0.001$). The majority of surgeons in both groups have similar positioning for all main points of the statement. However, the agreement proportions for the preceptors responsibility during the procedures were higher among non-robotic surgeons that expected the preceptor to assume co-responsibility for the procedure (85% versus 60.9%, $p<0.001$), and intervene during the procedure as much as necessary (97.5% versus 91.7%, $p=0.033$). **Conclusion:** the overall agreement of the answers to the AMB statement seems to be a promising pathway to increase the participation of the medical entities into the robotic certification in Brazil.

Keywords: Robotics. Certification. Minimally Invasive Surgical Procedures. Training Support.

INTRODUCTION

Since its first use in 1985, robotic surgery in humans has been in the spotlight of the surgical community¹. The acceptance of robotic surgery has improved the portfolio of minimally invasive surgery and become the counterpoint to laparoscopy. Although its attractiveness has increased, currently with more than 5,000 thousand units worldwide, its cost and access to the robotic certification has limited the robotic use. The robotic

platform da Vinci® was approved by the Food and Drug Administration – USA (FDA) in 2000, and its recommendation by the National Institute for Health and Care Excellence – UK (NICE) in 2015. These are two important landmarks for robotic acceptance and worldwide diffusion.

Meanwhile, robotic surgery has become more common in Brazil, in many different specialties, and the Associação Médica Brasileira (AMB - Brazilian Medical Association) published a statement about the robotic

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certification process in Brazil, in December 2019². All surgical societies that use robotic platforms together with the AMB published a new robotic certification statement to grant future robotic surgeons and societies, in their respective areas of expertise, the ability to certify the professionals². This study aimed to evaluate the opinion and knowledge, in regard to the new directives of the AMB, among Brazilian surgeons who are members of the Colégio Brasileiro de Cirurgiões (CBC - Brazilian College of Surgeons). This was a web-survey.

METHODS

A national web-based cross-sectional survey was carried out, and the questionnaires were sent by e-mail to all members of the CBC. The first step was to send an invitation to all members of the College including a link to the survey; and the second step was to resend the invitation for those members who had received the email, but had not opened it, as depicted in Figure 1.

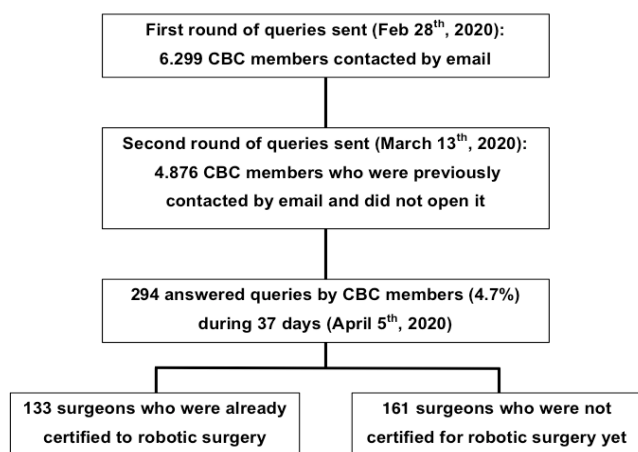


Figure 1. Data collection strategy. Colégio Brasileiro de Cirurgiões (CBC - Brazilian College of Surgeons).

This study was done by the Minimally Invasive and Robotic Surgery Committee of the CBC. All members were informed about both the anonymous status of their information and their responsibility regarding the accuracy of the given information. The survey addressed demographics, years of profession and robotic training, geographical distribution, robotic training, surgical volume information, and also questions about their knowledge and opinion regarding the new robotic surgical training

determination, in Brazil, according to the AMB statement published on December 17th, 2019. The latter was directed to all surgical societies that use robotic surgery, as described in Table 1.

The statistical analyses for baseline characteristics were performed by Fisher's exact test for categorical variables, and the Wilcoxon rank-sum test to examine continuous variables. Values were appropriately expressed as percentages or, as medians (interquartile ranges). For all analyses, p-value < 0.5 was considered significant, and the STATA software version 14.0 (StataCorp, College Station, TX) was used.

RESULTS

Out of the 6,299 CBC members who received the invitation to participate in the months of March and April 2020, 294 (4.7%) answered the query. The invitation process is described in Figure 1. The answers were split into two groups: 133 (45.3%) answers were of members who had already received robotic console certification, and 161 (54.8%) who did not have it. The overall distribution was also divided into the groups of surgeons who had or did not have robotic certification, and this is depicted in Table 2. Regarding the age of surgeons who answered the query, there was no difference between the two groups, as the overall median age was 46 (interquartile of 41 – 55, range of 30 – 77). However, when the time of experience as physician (years after graduation) was evaluated, the non-certified robotic group had more surgeons with at least 30 years of experience than the robotic (32.3% versus 23.3%, p=0.033). Although no disparities were seen regarding the major geographic country areas, surgeons with robotic certification more frequently worked in cities with at least one million inhabitants than those who were not certified (85.7 versus 63.4%, p<0.001).

The acquaintance with the robotic recommendations and regulations were also evaluated as depicted in Table 2. Most of the surgeons (95.6%) in both groups were aware of the FDA recommendations for the use of robotic surgery as a valid therapeutic option, as long as the surgical team receives appropriate training and certification. Concerning surgeons who were aware of both the NICE recommendation and the approval of AMB robotic statement, the robotic certified group more

frequently reported being aware of both than those in the non-robotic group, respectively, 98.5% and 75.9% versus 88.5% and 40.4%, $p=0.001$ and $p<0.001$.

Both groups had similar positioning for all the main topics of the statement regarding the AMB statement and the other recommendations, as demonstrated in Table 3. Nonetheless, the agreement for the mentorship responsibility during the procedures was different between groups. Non-robotic surgeons expected that the mentor should take over the co-responsibility for the procedure (85% versus 60.9%, $p<0.001$) than the certified robotic surgeons. The former also expected the mentor to intervene during the procedure as much as

necessary (97.5% versus 91.7%, $p=0.033$).

Regarding the certified robotic surgeons' group, an overview of years of experience as a physician and after robotic training is depicted in Figure 2. The median number of procedures is 20, with a mean number of 115 procedures. Most of the surgeons (65.4%) work in more than one area, as described in Table 4. Upper gastrointestinal (63.2%), hernia (60.9%), and colorectal (57.9%) operations represented the three most common surgical procedures described by the robotic expert group. The majority of the surgeons (82.7%) who work with robotic surgery have the opinion that the robotic platform has been a useful tool to improve their surgical skills.

Table 1. Guidelines of the Associação Médica Brasileira (AMB - Brazilian Medical Association) for certification in robotic surgery in Brazil.

The minimum requirements for qualification in robotic surgery regardless the surgical specialty

1. The qualification in robotic surgery must be linked to the surgeon's specialty in the medical council.
2. The training has to be recognized by a specialty society.
3. The surgeon must have theoretical and hands on training with the components of the robotic platforms, and their operation.
4. Minimum of established hours on the simulator training platform.
5. Observation of a preceptor surgeon for a minimum number of surgeries, according to the specialty.
6. Minimum number of surgeries performed under the supervision of a preceptor surgeon.
7. The preceptor surgeon must demonstrate minimal experience in the specialty, and his certification must be certified by the AMB.
8. The use of animals is not mandatory.
9. A provisional license will be issued until the surgeon completes the requirements to receive the definitive license
10. The preceptor surgeon will be co-responsible with the training surgeon, for any damage to the patient, caused by robotic surgery.
11. The patient must be informed, in a specific document, that the training surgeon, under the supervision of the preceptor surgeon, will perform the surgery.
12. Hospital's medical director must inform the training surgeon, that the preceptor will coordinate the surgical procedure, documenting with everyone's signature.
13. The preceptor surgeon must direct the surgical actions, whenever he deems convenient, for patient safety.
14. All medical staff, including anesthetist and assistant surgeon, must be trained by the guidelines of the AMB.

Table 2. Demographic characteristics of the 294 Brazilian surgeons who answered the query of the Colégio Brasileiro de Cirurgiões (CBC - Brazilian College of Surgeons) about the new certification process for robotic surgery in Brazil and their acknowledgement of the actual robotic recommendations.

Characteristics	Total N=294 (%)	Robotic Group N=133 (45.3%)	Non-robotic Group N=161 (54.8%)	p-value
Age – years*	46 (41 – 55)	46 (41 – 54)	46 (40 – 57)	0.785
Years after graduation				0.033
≤ 5	14 (4.8)	3 (2.3)	11 (6.8)	
>5 and ≤ 10	21 (7.1)	6 (4.5)	15 (9.3)	
>10 and ≤ 15	37 (12.6)	17 (12.8)	20 (12.4)	
>15 and ≤ 20	61 (20.8)	34 (25.6)	27 (16.8)	
>20 and ≤ 25	46 (15.7)	27 (20.3)	19 (11.8)	
>25 and ≤ 30	32 (10.9)	15 (11.3)	17 (10.6)	
>30	83 (28.2)	31 (23.3)	52 (32.3)	
Major Brazilian Regions ^a				0.71
North	9 (3.1)	1 (0.8)	8 (5)	
Northeast	11 (3.8)	4 (3)	7 (4.4)	
Central-west	24 (8.2)	7 (5.3)	17 (10.6)	
Southeast	217 (74)	107 (80.4)	110 (68.7)	
South	31 (10.9)	14 (10.5)	18 (11.3)	
Population x10 ³ inhabitants				<0.001
≤ 200	22 (7.5)	1 (0.7)	21 (13)	
> 200 and ≤ 500	31 (10.5)	9 (6.8)	22 (13.7)	
> 500 and ≤ 1,000	25 (8.5)	9 (6.8)	16 (9.9)	
> 1,000	216 (73.5)	114 (85.7)	102 (63.4)	
Recognition and acquaintance with the new process of robotic surgery in Brazil				
NICE recommendation for robotic approach (2015) ^b				0.001
Yes	268 (93.1)	130 (98.5)	138 (88.5)	
No	20 (6.9)	2 (1.5)	18 (11.5)	
FDA approval for robotic surgery (2019)				0.236
Yes	282 (95.9)	130 (97.7)	152 (94.4)	
No	12 (4.1)	3 (2.3)	9 (5.6)	
AMB statement				<0.001
Yes	166 (56.5)	101 (75.9)	65 (40.4)	
No	128 (43.5)	32 (24.1)	96 (59.6)	

*reported as median and interquartile; ^an=293; ^bn=288; NICE: National Institute for Health and Care Excellence (UK); FDA: Food and Drug Administration (USA); and AMB: Associação Médica Brasileira (AMB - Brazilian Medical Association).

DISCUSSION

The use of the robotic platform has increased with many articles and societies supporting its use, worldwide. The evolution of robotic surgery has taken place in the last 35 years, with some different robotic platforms³. The first human robotic surgery was performed in 1985 using a Programmable Universal Machine for

Assembly (PUMA 200), that was used to carry out a neurosurgical biopsy¹. The system was preoperatively programmed based on fixed anatomy landmarks, and this explains why it could not be applied to general surgery³. In this regard, the need for fixed landmarks limited the application for abdominal and thoracic surgery, since in both anatomic areas, the pneumoperitoneum leads to organ mobilization and deformation which was an

important drawback. Although the first human robot-assisted cholecystectomy was performed in Belgium using an Intuitive prototype called "Mona", the FDA approved the da Vinci® platform as robot-assisted surgery for general surgery, after at least 300 surgeries, on July 17th, 2000. In 2001, the first robot-assisted telesurgery was

carried out by a surgeon on the console in New York and the patient in Strasbourg, France, using the prototype ZEUS (Computer Motion, California)⁴. In 2003, both Computer Motion and Intuitive merged their business, and the da Vinci® platform was launched while the Zeus was discontinued.

Table 3. Proportion of agreement with the recommendations of the Associação Médica Brasileira (AMB - Brazilian Medical Association) statement (2019) of robotic surgical certification in Brazil.

Query	Total N=294 (%)	Robotic Group N=133 (45.3%)	Non-robotic Group N=161 (54.8%)	p-value
Training and certification to robotic platform by*				0.302
Industry (actual)	5 (2.5)	4 (4.7)	1 (0.9)	
Medical entities	193 (94.6)	80 (93)	113 (95.8)	
Medical entities + industry	5 (2.5)	2 (2.3)	3 (2.5)	
Without opinion	1 (0.5)	0	1 (0.9)	
Acquaintance with the CBC & other medical societies				0.217
Yes	268 (91.2)	118 (88.7)	150 (93.2)	
No	26 (8.8)	15 (11.3)	11 (6.8)	
Need of the specialist registration into the Regional Medical Council				1
Yes	278 (94.6)	126 (94.7)	152 (94.4)	
No	16 (5.4)	7 (5.3)	9 (5.6)	
Need of provisory habilitation ^a				0.893
Yes	219 (74.7)	100 (75.2)	119 (74.4)	
No	74 (25.3)	33 (24.8)	41 (25.6)	
Preceptor as co-responsible of the surgical procedure ^a				<0.001
Yes	217 (74.1)	81 (60.9)	136 (85)	
No	76 (25.9)	52 (39.1)	24 (15)	
Preceptor on duty of intervention during the surgical procedure ^a				0.033
Yes	278 (94.9)	122 (91.7)	156 (97.5)	
No	15 (5.1)	11 (8.3)	4 (2.5)	
Need of training of the surgical team ^a				0.624
Yes	250 (85.3)	112 (84.2)	138 (86.3)	
No	43 (14.7)	21 (15.8)	22 (13.7)	

*n=204; ^an=293, Colégio Brasileiro de Cirurgiões (CBC - Brazilian College of Surgeons).

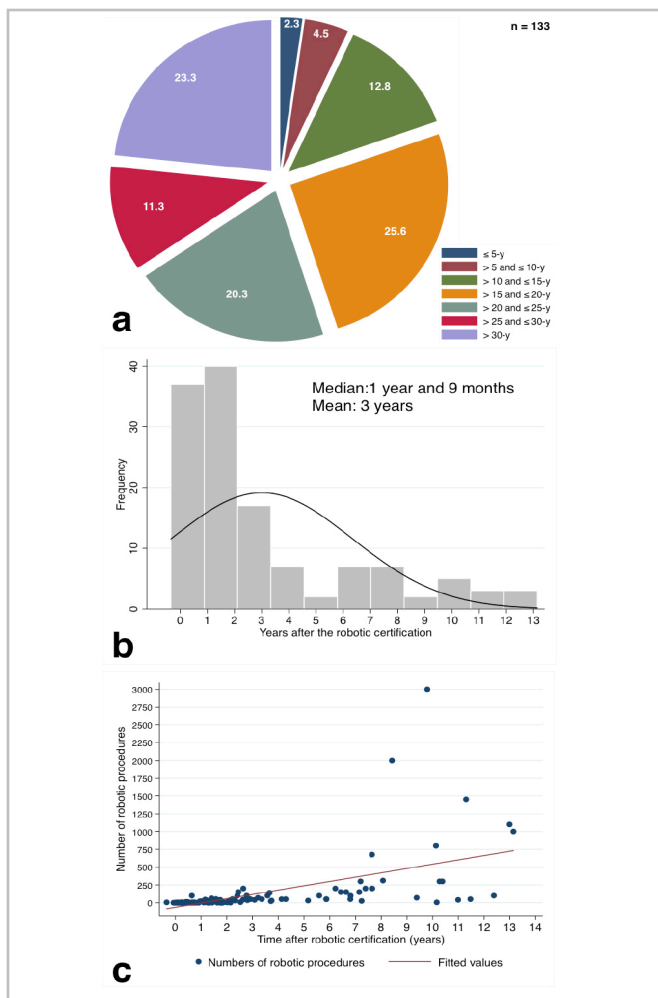


Figure 2. Surgical experience among the 133 surgeons who have robotic certification. 2a: distribution of surgeons according to the time after medical graduation; 2b: distribution of surgeons according to the time after robotic certification; and 2c: scatterplot of the total number of procedures by each surgeon according to the time after robotic certification.

The main putative advantage of the robotic system is the tridimensional view since two cameras are used to provide a more precise surgical field view when compared to the dimensional laparoscopic view, both using the magnification; the stability of the image is an important aspect since the camera is also operated by the surgeon and its motion can be static as much as the surgeon wants it. The robotic platform increases both the ergonomics and coordination of the surgical team; and perhaps the most valuable contribution of the system is the Endo Wrist technology that preserves the movements of the human hand-pincers, with more degrees of freedom than laparoscopy. On the other hand, the limitations of the tactile sensation in robotic surgery

Table 4. Distribution of robotic group (133 surgeons) according to the acting areas of surgery and impression about robotic surgery.

Number of acting area by surgeon (%)	
1	46 (34.6)
2	10 (7.5)
3	16 (12)
4	26 (19.6)
5	28 (27.1)
6	7 (5.3)
Number of surgeons by each acting area (%)	
Upper Gastrointestinal (Esophagus and Stomach)	84 (63.2)
Hernia	81 (60.9)
Colorectal	77 (57.9)
Cholecystectomy	62 (46.6)
Hepato-Pancreato-Biliary (Liver, Bile Ducts and Pancreas)	51 (38.3)
Gynecology	25 (18.8)
Urology	11 (8.3)
Thoracic	6 (4.5)
Head and Neck	3 (2.3)
Personal impression about the robotic approach in their surgical practice	
No differences in practice	13 (9.8)
More difficult than laparoscopy	10 (7.5)
Overall improvement	110 (82.7)

are more important than with the laparoscopic approach, which is also limited. The development of new eye-haptic skill for the robotic approach is a common skill usually assimilated in the learning curve⁵.

Another limiting issue of robotic acceptance and diffusion is the higher costs compared to laparoscopy. Although the costs to pay for the initial investments regarding acquisition and maintenance of the robotic platforms, their diffusion in both Eastern and Western countries has increased. There are currently 5.669 da Vinci® platforms in the world, and 74 in Brazil, on March 31, 2020⁶. In Brazil, there are about 1,500 certified surgeons to perform robotic surgery, and near 10% answered this web-national survey.

Our survey arose from the need to assess the knowledge concerning the new BMA statement among the surgeons. This statement declares common points that must be adopted by all the medical societies that use the robotic platform as a modality of treatment. The overall distribution of the surgeons indicated that most of them live in bigger cities, with more than one million inhabitants, from the Southeast of Brazil, and with at least 10 years of medical practice. Moreover, most of them stated they were aware of the approval of the robotic platform by FDA and the NICE. The majority of the surgeons also agreed with the importance of the training and certification provided by medical entities, regardless CBC or not. The surgeons stated there is a need to at the medical council on subject specialty, agree with the need for a provisory license, the need of training of the whole surgical team, not only for the main surgeon, and the role of the preceptor as co-responsible for surgical procedure and on duty for intervention as much as necessary.

However, expecting a putative biased view between surgeons who performed or not robotic surgery, both groups were compared on the survey. The main differences are that the robotic group has fewer surgeons with more than 30 years practice; more surgeons working in bigger cities; more surgeons demonstrated awareness of the NICE recommendations and knowledge about the AMB statement. Although the majority of both groups agreed about the preceptor as co-responsible and on duty for intervention as much as needed, the agreement proportion for them was higher and the non-robotic group. These answers suggest that the referee physician of the patient is concern about the involvement of the preceptor in the surgical outcome, as well as they, are also a concern to receive the appropriate aid during the intervention as much as necessary. Although the proctoring assumes a role in the development of new surgical skills, it is not simply characterized as training since all physicians involved in the procedure have co-responsibility with the health of the patient, regardless of their role as a surgeon, assistant, preceptor or anesthesiologist.

Regarding specifically the robotic group, they represented approximately 9% of the surgeons certified for robotic surgery in Brazil, being 80.4% in the Southeast, and 85.4 % working in cities with at

least one million inhabitants, that it is also close to the overall distributions of the 74 robotic platforms in Brazil with 71% in the Southeast; 13% in the combined North/Northeast; 8% in the Central-West; and 8% in the South of Brazil⁶. Concerning a surrogate for surgical experience, years after medical graduation and years after robotic certification were measured, most of them were between 10 to 20 years after graduation and they represented, mostly, surgeons with approximately 21 months with experience in robotic surgery. Only one-third of them work exclusively in one sub-area of general surgery and specialties. It corroborates with both the scope of the CBC and the overall general surgery practice in Brazil, in which the surgeons usually work in more than one of the subarea listed in this survey. The majority of the robotic surgeons, as demonstrated in Figure 2, still have little experience (median of 20 procedures) that it opposes for few surgeons with higher volume, given rise to a skewed distribution for a mean number of procedures (115 procedures). Regarding the personal impression of the robotic platform in their surgical practice, 80% of the surgeons noticed an overall improvement of their technical skills with its use.

The limitations of this study are those related to cross-sectional studies, thus, causal relationships were not possible. Neither surgical indications nor surgical outcomes were the scope of this survey since the objective was the approach to the new regulation process for robotic surgery in Brazil and not the results from robotic surgery itself. Although a previous study suggests the responders of web-survey have more interest if they expertise and clinical practice in the subject area, the majority of the surgeons who answered this national web-survey did not have robotic certification⁷. Contrary, although both groups have a different profile, many surgeons who have not performed robotic surgery have interest and concern about this topic. Perhaps the most important limitation of our study was low number of answers, representing 4.7% of CBC members. However, looking at the robotic group, they represent almost 9% of robotic surgeons certified in Brazil. Both numbers of total and robotic groups were beneath our initial expectations, and its fact claims for more participation of CBC members in collaborations from CBC rather than this small subgroup. By contrast, even this small number was large enough to

detect significant differences between groups and also to show that the transition for the new robotic certification process in Brazil should have support for both certified and not-yet certified surgeons in Brazil.

While some differences were detected, mainly for the profile of each group, the similarities especially for both acknowledgment and acceptance for the new

regulation is crucial and favorable to the transition of the new certification process in Brazil. They are congruent with the interest of both AMB and CBC members. This survey and its overall agreement to the AMB statement seem to be a promising pathway to increase the participation of the medical entities into the robotic certification process in Brazil.

R E S U M O

Objetivo: avaliar o perfil do cirurgião robótico brasileiro e seu reconhecimento sobre o novo processo de certificação para cirurgia robótica que consta na declaração da Associação Médica Brasileira (AMB). De acordo com a declaração da AMB, as sociedades médicas e os preceptores devem alcançar papéis de liderança no treinamento e certificação de cirurgiões, atuando em parceria com a indústria. **Métodos:** uma pesquisa nacional pela Internet foi promovida pelo Colégio Brasileiro de Cirurgiões com seus membros. **Resultados:** entre as 294 respostas, os cirurgiões foram divididos em dois grupos: 133 (45,3%) que possuíam certificação de console robótico e 161 (54,8%) que não possuíam. A média geral de idade foi de 46 anos, mas o grupo não robótico teve mais cirurgiões com pelo menos 30 anos de experiência (32,3% versus 23,3%, $p = 0,033$). Cirurgiões com certificação robótica trabalhavam mais frequentemente em cidades mais populosas, com pelo menos um milhão de habitantes (85,7 versus 63,4%, $p < 0,001$). A maioria dos cirurgiões de ambos os grupos tem posicionamento semelhante para todos os pontos principais da declaração. No entanto, as proporções de concordância para a responsabilidade do preceptor durante os procedimentos foram maiores entre os cirurgiões não robóticos que esperavam que o preceptor assumisse corresponsabilidade pelo procedimento (85% versus 60,9%, $p < 0,001$), e que intervenha, tanto quanto necessário (97,5% versus 91,7%, $p = 0,033$). **Conclusão:** a aceitação por parte da maioria dos profissionais em relação à declaração da AMB parece ser caminho promissor para aumentar a participação das entidades médicas na certificação robótica no Brasil.

Palavras chave: Certificação. Procedimentos Cirúrgicos Minimamente Invasivos. Robótica. Treinamento por Simulação.

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