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Luciano Rodrigo Peres Arruda
Hospital Santa Marcelina

Giselle Coelho
Santa Marcelina Hospital - São Paulo; Brazil

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Luciano Rodrigo Peres, Wilson Mello Alves Junior, Giselle Coelho & Marcos Lyra

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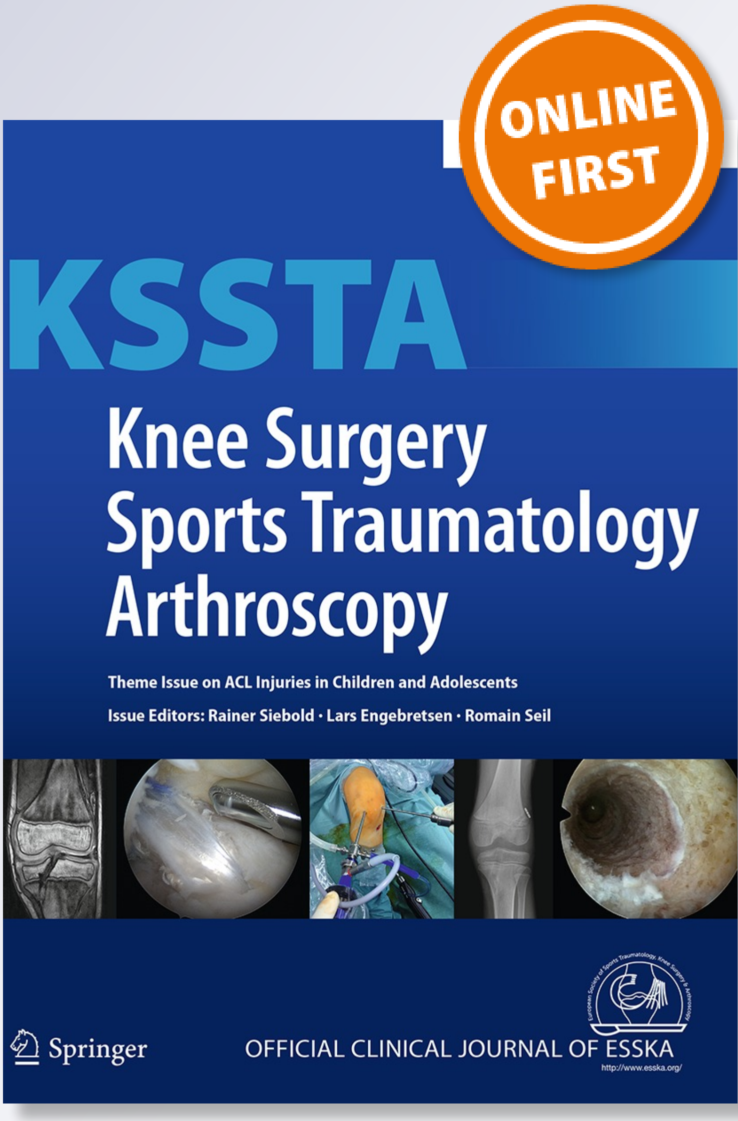

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A new simulator model for knee arthroscopy procedures

Luciano Rodrigo Peres[1] · Wilson Mello Alves Junior[1] · Giselle Coelho[1] · Marcos Lyra[1]

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Abstract
Purpose Arthroscopy is currently the "gold standard" for various surgeries performed on the knee joint. Therefore, surgeons wishing to operate in this professional field should be able to perform this technique. Arthroscopic training, an experimental laboratory, is important for the surgeons' training, enabling them to increase their skills with the specific instruments and to become familiar with the operating techniques. The aim of this study was to present a new surgical simulator for training in arthroscopic procedures of the knee.
Methods The Kneetrainer 1 is a simulator consisting of a type of thermo-retractile, thermo-sensitive synthetic rubber that has texture, colour, consistency, and mechanical resistance that mimic many human tissues. Nine simulators were used, operated by seventeen expert Brazilian surgeons in knee surgery. The surgeons performed arthroscopy, meniscectomy, and reconstruction of the anterior cruciate ligament (ACL), responded to an electronic questionnaire with several variables, and gave an overall score on the ability of the device to perform realistic simulation for the above procedures.
Results The ability to perform the procedures of meniscectomy and ACL reconstruction was considered adequate by 82 and 100 % of the specialists, respectively. The overall scores for the ability to perform realistic simulation for the procedures meniscectomy and reconstruction of the anterior cruciate ligament by arthroscopy were 64.7 and 82.4 %, respectively. The simulator was therefore considered suitable for practical application with novice surgeons.
Conclusion The Kneetrainer 1 simulator was assessed as an effective tool for recreating accurate arthroscopic knee procedures. In addition, the simulator may be effective as a means of honing the skills of novice surgeons. Future investigations should be performed to validate the reliability of the simulator.
Level of evidence IV.

Keywords Simulation surgery · Arthroscopy · Anterior cruciate ligament · Meniscectomy · Scientific validation · Novice surgeons

Abbreviation
ACL Anterior cruciate ligament

Introduction

Arthroscopy is a widely used surgical procedure performed by orthopaedists, especially with respect to knee surgery, and remains the gold standard for treatment of meniscal injuries and anterior cruciate ligament (ACL) reconstructions. However, to perform this surgical technique with safety and precision, practicing it in an experimental model prior to implementation of the real procedure is crucial. Therefore, trainee orthopaedic surgeons should have access to good experimental models as a means of improving surgical skill. In this regard, several mechanisms have been used to reach maturity of these professionals, but some methods used for decades are not efficient, making it outdated due to anatomical differences, the use of animals and cadavers [18], and the high costs and ethical reasons [1–13].

✉ Luciano Rodrigo Peres
peresluciano@hotmail.com

1 Scientific Innovation and Education Development Institute (SIEDI), Rua George Ohm 230. Torre B CJS 121 e 122 - Cidade Monções, São Paulo, SP CEP: 04576-020, Brazil

Several simulators are being created due to robotics evolution and medical equipment industry, with the aim of adding value to the learning curve of professionals working in surgical specialties [4, 13]. Virtual, synthetic, and realistic simulators are accessible. However, in the orthopaedic surgery field, realistic simulators are not yet available, and as much as virtual models are consolidated in the literature, they have some disadvantages [5, 14–16].

The ideal simulator is accessible, low cost, and non-toxic. In particular, it must be able to reproduce a surgical situation as close to that of reality as possible. Furthermore, the simulator must be useful for inexperienced surgeons and for the development of new techniques for experienced surgeons [11]. Synthetic simulators present a feasible alternative for use in surgical training, with a number of key advantages. Whilst some synthetic models exist [19], many fail to simulate sensation through several anatomical layers of the knee realistically.

This study aims to test a new thermo-retractile, thermo-sensitive synthetic rubber simulator, the Kneetrainer 1, and to evaluate if it has sufficient anatomical and realistic correlations with the human knee for training in meniscal and ACL surgeries.

Materials and methods

This study was developed to introduce Kneetrainer 1 as a possible simulator for knee surgery procedures. All data were collected from January 2014 to September 2015 at Scientific Innovation and Education Development Institute (SIEDI) in São Paulo, Brazil.

The Kneetrainer 1 is a simulator consisting of a type of thermo-retractile, thermo-sensitive synthetic rubber (Neoderma® - ProDelphus Company) that, when combined with different polymers, produces more than 30 different formulas. These formulas exhibit textural, colour, consistency, and mechanical resistance characteristics that mimic many human tissues. The plastic moulds used to manufacture bones of the model were made from the human bone, and they constitute the basic structure of this simulator. Further, the model includes other anatomical structures, such as the menisci and joint capsule, enabling distension for the infusion of saline solution, thereby making recreations of the arthroscopic procedure, and surgeries involving the cartilage, ligaments, and muscles, more realistic. The knee is mounted on an acrylic base with a swivel stand that allows knee flexion to 120° proximally, and a foot located distally.

Kneetrainer 1 model involved the use of nine simulators operated by 17 expert Brazilian knee surgeons. The criteria defining an expert required: (1) a specialization title in knee surgery from the Brazilian Knee Surgery Society, (2) current occupation of a university or hospital teaching position, involved in the education of knee surgery residents, and (3) having performed more than 150 arthroscopic procedures [10]. Specialists performed three procedures using the simulator: arthroscopy, meniscectomy, and ACL reconstruction. All instruments and materials used in conventional surgery were available, as a means of ensuring the simulation was as realistic as possible.

Following completion of the procedures, the surgeons responded to an electronic questionnaire with 18 questions as explained by the authors and voted on each of the variables previously defined using a keypad.

Sample size calculation

Sample size calculation was performed to support the number of surgeons in the study. In São Paulo, there are around 1000 full professors in knee surgery. From these 1000 surgeons, 20–30 % are renowned in the international literature. For this reason, we used around 10 % of the surgeons. The standard deviation for the difference between the scores was 20 % (calculated from population control), with a confidence interval of 95 and 80 % power, the number of participants to detect a measurable sensitivity was calculated in seventeen surgeons. Assuming a loss rate and waiver of 10 %, the study was considered complete when 17 doctors joined the research.

Questionnaire sensitivity

Cronbach's alpha is a method used to check the internal consistency of the data. This method has been widely used to estimate the reliability of measuring instruments. Before beginning the results, we defined a standard error of 5 %. The internal consistency of the questionnaire of 18 questions was calculated at $\alpha = 0.45$. Two ratio equality tests were applied to characterize the distribution of relative frequencies (percentages) of all questions.

Clinical and anatomical evaluations questionnaire

The following aspects were evaluated: consistency, resistance, tactile identification, applicability of the simulator for training novice surgeons, and an overall score of realistic simulation capacity (Tables 1, 2, 3), for the procedures described above. Consistency was defined as the degree of density or firmness of the material that the simulator exhibited. Resistance was defined as the behaviour of simulator

Table 1 Scoring scale for variables of tactile identification

Variable	Score	Description
Resistance		
	1	Softer than the normal tissue
	2	Harder than the normal tissue
	3	Different from the normal tissue, but without affecting the simulation
	4	Similar to the normal tissue, without need for structural alteration
Consistency		
	1	No resistance compared to the normal tissue
	2	More resistance than the normal tissue
	3	Less resistance than the normal tissue
	4	Differing resistance compared to the normal tissue, but without affecting the simulation
	5	Similar to the normal tissue, with no need for structural alteration

Table 2 Description of anatomical and surgical parameters

Question	Reply
Size of the model	Adequate or inadequate
Form	Adequate or inadequate
Surgical procedure evaluated: arthroscopic meniscectomy	Adequate or inadequate
Surgical procedure evaluated: arthroscopic ACL reconstruction	Adequate or inadequate
Do you know of any other another surgical simulator like the Kneetrainer 1?	Yes or no
Do you think the Kneetrainer 1 is able to generate skills and/or alter attitudes among trainee surgeons?	Yes or no

Table 3 Overall score for the ability to perform realistic simulation

Score	Description
1	Simulator presents significant distortions (more than 4 items with minimum score) when compared to the real anatomical structure, requiring several alterations, and making it unsuitable for practical application with inexperienced surgeons
2	Simulator presents minor distortions (up to 4 items with minimum score) when compared to the real anatomical structures, requiring alterations to make it suitable for practical application with inexperienced surgeons
3	Simulator presents distortions (<2 items with minimum score) when compared to the actual anatomy, but is suitable for practical application with inexperienced surgeons, and does not affect the analysis
4	Simulator is very similar to the real anatomical structure, and therefore suitable for practical application with inexperienced surgeons

structures to procedural stresses and strains. To be considered adequate for a procedure, the simulator must be able to reproduce similar anatomy and surgical techniques as those required in the equivalent real procedure.

Statistical analysis

Cronbach's alpha was used to verify the internal consistency of the questionnaire consisted of 18 questions. The two proportion equality test (Chi-square) was used as a means of comparing the proportion of answers for two specific variables. Data are presented as absolute and percentage. Differences were considered significant at $P < 0.05$.

Results

Cronbach's alpha showed a good internal consistency and reliability of the questionnaire (value of 0.444; "Appendix").

The ability to perform procedures of meniscectomy and ACL reconstruction was considered adequate by 14 (82.4 %, $P < 0.001$) and 17 (100 %, $P < 0.001$) of the specialists, respectively.

Overall scores for evaluation of the ability to perform a realistic simulation for the procedures of meniscectomy and arthroscopic ACL reconstruction were 11 (64.7 %, $P =$ NS) and 14 (82.4 %, $P < 0.001$), respectively. (Figs. 1, 2).

Statistical examination established that the model is effective as a realistic simulator for inexperienced surgeons, and that it presents an overall score for ability to perform realistic simulation of more than 50 %, considering the sum of items 3 and 4 (Table 3).

With regard to consistency of the material, 10 (59 %) participants believed that minor differences from normal tissue were apparent, but did not believe that this would affect surgical simulation, or that structural alterations would be required (Table 4).

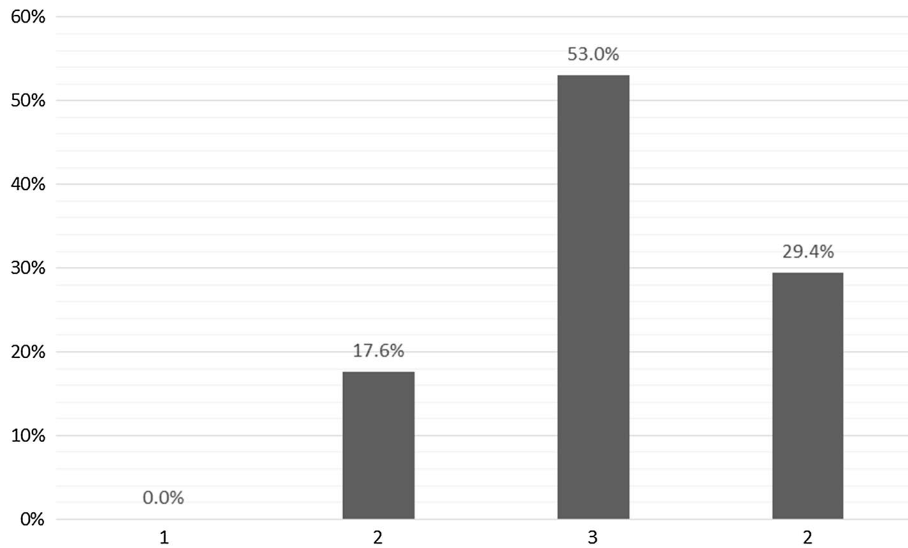

Fig. 1 Distribution of scores for the ability to perform realistic simulation in arthroscopic meniscectomy procedures. *1* Simulator presents significant distortions (more than 4 items with minimum score) when compared to the real anatomical structure, requiring several alterations, and making it unsuitable for practical application with inexperienced surgeons. *2* Simulator presents minor distortions (up to 4 items with minimum score) when compared to the real anatomical structure, requiring alterations to make it suitable for practical application with inexperienced surgeons. *3* Simulator presents distortions (<2 items with minimum score) when compared to the actual anatomy, but is suitable for practical application with inexperienced surgeons, and does not affect the analysis. *4* Simulator very similar to the real anatomical structure, and therefore suitable for practical application with inexperienced surgeons

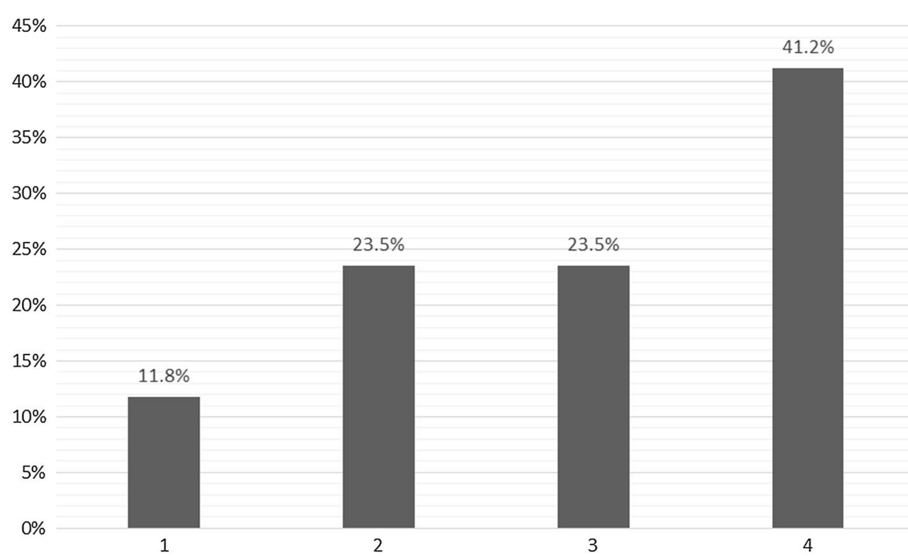

Fig. 2 Distribution of scores for the ability to perform realistic simulations in arthroscopic ACL procedures. *1* Simulator presents significant distortions (more than 4 items with minimum score) when compared to the real anatomical structure, requiring several alterations, and making it unsuitable for practical application with inexperienced surgeons. *2* Simulator presents minor distortions (up to 4 items with minimum score) when compared to the real anatomical structure, requiring alterations to make it suitable for practical application with inexperienced surgeons. *3* Simulator presents distortions (<2 items with minimum score) when compared to the actual anatomy, but is suitable for practical application with inexperienced surgeons, and does not affect the analysis. *4* Simulator very similar to the real anatomical structure, and therefore suitable for practical application with inexperienced surgeons

Table 4 Results of the evaluation of consistency in the various items analysed

Item analysed	Softer than the normal tissue (%)	Harder than the normal tissue (%)	Different from the normal tissue, but without affecting the simulation (%)	Similar to the normal tissue, without the need for structural alteration (%)
Menisci	(8) 47.1	(0) 0**	(6) 35.3	(3) 17.6
ACL	(1) 5.9*	(2) 11.8*	(10) 58.8	(4) 23.5**
Tactile identification of the external structures	(10) 58.8	(0) 0**	(6) 35.3	(1) 5.9**
Tactile identification of other structures in arthroscopy	(7) 41.2	(0) 0**	(8) 47.1	(2) 11.8*

* $P < 0.05$; ** $P < 0.01$

Table 5 Results of the evaluation of resistance in the various items analysed

Item analysed	No resistance compared to the normal tissue (%)	More resistance than the normal tissue (%)	Less resistance than the normal tissue (%)	Different resistance from the normal tissue, but without affecting the simulation (%)	Similar to the normal tissue, without the need for structural alteration (%)
Menisci	(3) 17.6	(0) 0**	(6) 35.3	(5) 29.4	(3) 17.6
ACL	(0) 0**	(3) 17.6*	(0) 0**	(5) 29.4	(9) 52.9
Tactile identification of the external structures	(3) 17.6	(2) 11.8, $P = 0.052$	(7) 41.2	(3) 17.6	(2) 11.8, $P = 0.052$
Tactile identification of other structures in arthroscopy	(1) 5.9**	(1) 5.9**	(6) 35.3	(9) 52.9	(0) 0**

* $P < 0.05$; ** $P < 0.01$

In relation to resistance of the material, 9 (53 %) of the surgeons were of the opinion that the anatomical structures of the simulator were different from the normal tissue, but without affecting the surgical simulation, or considered the material similar to the normal tissue, without a need for structural alteration (Table 5).

In terms of morphology of anatomical structures within the simulator, compared to the real equivalents, the participants evaluated the simulator as adequate, with scores of 94 and 82.5 % for size and shape, respectively.

Sixteen participants (94 %, $P < 0.001$) felt that the use of the simulator evaluated would aid in the generation skills and/or alter the attitudes of trainee surgeons.

Discussion

The most important finding from the present study was a 94 % (16 of 17 participants) positive response rate concerning the ability of Kneetrainer 1 to generate skills and/or alter the attitudes of trainee surgeons. The current methodology of surgical learning is based on the so-called see one, do one, teach one approach. This educational approach has been considered the gold standard for surgical training of orthopaedic residents interested in knee surgery [17]. This approach has become consecrated over time, in which skilled mentors provide practical demonstrations and share theoretical knowledge with their trainees. Therefore, the surgical procedure has typically been learnt with an example and repetition-based methodology. However, this model of training requires a large number of varied cases to produce a capable new surgeon [7, 8, 17]. Hernandez and Rezende, in a study on knee arthroscopy, concluded that a surgeon can only be considered fully qualified for this type of procedure after he or she has completed 150 knee arthroscopies [10].

The models currently available for training (cadaver, animal, and virtual) have advantages and disadvantages as represented in Table 6 [2, 13, 18]. The synthetic model is a viable low cost, non-toxic, safe, and ethical alternative that enables training to be delivered in varying locations, not restricted to specific hospitals or university laboratories, as is the case with cadavers and experimental animals (Table 6) [3, 9].

The Kneetrainer 1 was developed with the aim of providing an additional tool for novice orthopaedic residents to practice arthroscopic knee surgery, and for training more experienced surgeons in new techniques. To this end, it is necessary to verify the surgical simulation model with surgeons who have experience in the main surgical procedures

Table 6 Advantages and disadvantages of various types of simulation

Type of simulation	Advantages	Disadvantages
Cadaveric (human and animal)	Accurate tissue representation, anatomical fidelity (human)	High cost, ethical concerns, need for additional staff and laboratory space, rare pathology, not reusable
Synthetic	Portable, reusable, pathology simulation possible	Poor tissue representation, sometimes not reusable
Virtual reality	Reusable, pathology simulation possible	High cost, technical maintenance, software subscriptions, haptic response still less realistic (but improving)

in question to ensure that the model is adequate for use with trainee surgeons, generating and/or modifying surgical skills.

Wong et al. [20] validated a model for specific training in tying knots during arthroscopy, in which the participating specialist surgeons agreed that the model, despite not being anatomical or accurately representing joint morphology, was suitable for this type of training [6]. A model of the knee joint, besides being effective for surgical training, is also believed to provide a realistic visual appearance and tactile sensation that not only enables the development of surgical techniques but also provokes sensory skill improvement in the apprentice. Therefore, the internal structures (menisci, ligaments, cartilage, etc.), shape, and size of the simulator must present a degree of anatomical correlation that is satisfactorily close to that observed in real anatomical structures.

Sixteen of the specialist cohort (94 %) considered the model adequate for both procedures evaluated (meniscectomy and ACL reconstruction), in terms of the anatomical considerations and structures, and the ability to perform realistic simulation of the surgeries in question. This was also noted in the overall scores relating to the ability to perform realistic simulations, with both procedures scoring greater than 50 %, for the sum of items 3 and 4 (64.7 and 82.4 %, respectively).

It is recognized a series of limitations of this study. The small sample size of participants should be increased in future investigations. Furthermore, this simulator was not compared with other existent simulators. These are topics to be addressed in future studies.

This study was conducted for presentation of the simulator. In our next study, we aimed to test the validation of Kneetrainer 1.

Conclusion

The Kneetrainer 1 simulator was assessed as an effective tool for recreating accurate arthroscopic knee procedures. In addition, the simulator may be effective as a means of honing the skills of novice surgeons.

Clinical relevance

The model presented in this study will provide greater contact, facility, and anatomical realism for students and specialists, in either regular training and major surgery or implementation of new techniques and surgical approaches for knee surgeons.

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Author contributions L.R.P. contributed to conception and design, acquisition of data, statistical analysis and interpretation of data, drafting of the manuscript, critical revision for important intellectual content, final approval of the manuscript to be published, and is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. W.M.A.J. contributed to conception and design, acquisition of data, statistical analysis and interpretation of data, drafting of the manuscript, critical revision for important intellectual content, final approval of the manuscript to be published, and is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. G.C. contributed to conception and design, acquisition of data, statistical analysis and interpretation of data, drafting of the manuscript, critical revision for important intellectual content, final approval of the manuscript to be published, and is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. M.L. contributed to conception and design, acquisition of data, statistical analysis and interpretation of data, drafting of the manuscript, critical revision for important intellectual content, final approval of the manuscript to be published, and is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest involved.

Appendix

Questionnaire

Simulator "Kneetrainer 1"

A. Tactile identification of the bone structures and soft tissues

- Consistency*
- Resistance**
- Size (Adequate/Inadequate)
- Form (Adequate/Inadequate)

B. Arthroscopic identification of structures and soft tissues

- Consistency*
- Resistance**
- Size (Adequate/Inadequate)
- Form (Adequate/Inadequate)

C. Meniscectomy

- Identification and characterization of the injury
- Consistency*
- Resistance**
- General procedure (Adequate/Inadequate)

D. ACL reconstruction

- Consistency*
- Resistance**
- Screw interference (Adequate/Inadequate)
- General procedure (Adequate/Inadequate)

E. Final questions

- Do you know other realistic simulator with the same surgical options? (Yes or No)
- Do you think the proper use of "Kneetrainer 1" is capable of generating skills and/or modify the attitudes of surgeons in training? (Yes or No)
- On a scale of 1 to 5, how would you rate the "Kneetrainer 1" as a surgical simulator realistic?

*Points:

1. Softened compared to normal tissue
2. Hardened compared to normal tissue
3. Amended compared to normal tissue but without prejudice to the simulation
4. Similar to normal tissues: without undergoing structural modifications

**Points:

1. Absence resistance when compared to normal tissue
2. Increased resistance when compared to normal tissue
3. Resistance reduction when compared to normal tissue
4. Resistance change compared to normal tissue but without prejudice to the surgical simulation
5. Similar to normal tissues: without undergoing structural modifications

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