ETHICAL AND LEGAL ASPECTS OF TELEMEDICINE APPLIED IN ORTHOPEDICS

ASPECTOS ÉTICOS E LEGAIS DA TELEMEDICINA APLICADA À ORTOPEDIA

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ABSTRACT

Due to the pandemic of COVID-19, many outpatient services were suspended, affecting hundreds of patients. As a result, several countries were forced to seek strategies to readapt their health systems, one of which was the expansion of telemedicine. Currently, telemedicine is used for several specialties, facilitating the treatment and follow-up of patients who have difficulty accessing it. Tele-orthopedics, telemedicine applied to the orthopedic specialty, allows orthopedic care to be offered to patients regardless of distance. By reducing travel time, waiting time, and costs, teleorthopedics presents high patient satisfaction, allowing greater rehabilitation effectiveness after surgery and treatment compliance. There is much information in the current literature about telemedicine's legal and ethical aspects, but it is fragmented. This article aims to present a general explanation of these legal and ethical aspects, emphasizing tele-orthopedics. The ethical principles of autonomy, beneficence, non-maleficence and justice must be respected, as well the privacy and confidentiality during a teleconsultation. In this respect, orthopedic surgeons should be governed by traditional moral and ethical precepts. Still, they must also adapt to the new norms and laws regulating telemedicine use. Level of Evidence V: Expert Opinion.

Descriptors: Telemedicine. Medical Ethics. Jurisprudence. Orthopedics.

RESUMO

Com a pandemia da COVID-19, muitos atendimentos ambulatoriais foram suspensos, afetando centenas de pacientes. Isso forçou diversos países a buscarem estratégias para readaptar seus sistemas de saúde e, uma delas, foi a expansão da telemedicina. Atualmente, a telemedicina está sendo utilizada para diversas especialidades, facilitando o tratamento e o acompanhamento de pacientes que possuem dificuldade de acesso. A tele-ortopedia, telemedicina aplicada à especialidade ortopédica, permite a oferta dos cuidados ortopédicos a pacientes independente da distância. Por reduzir tempo de viagem, tempo de espera e custos, a tele-ortopedia, apresenta alta satisfação por parte pacientes, o que permite maior efetividade na reabilitação após cirurgias e adesão ao tratamento. Há na literatura atual diversas informações acerca dos aspectos legais e éticos da telemedicina, contudo são informações fragmentadas. Este artigo visa proporcionar uma explanação geral sobre esses aspectos éticos e legais, com ênfase na tele-ortopedia. Os princípios éticos da autonomia, beneficência, não-maleficiência e justiça devem ser respeitados, da mesma forma a privacidade e confidencialidade durante uma teleconsulta. Com isso, os ortopedistas devem ser regidos pelos tradicionais preceitos morais e éticos, mas também, devem se adequar as novas normas e leis que regulamentam o uso da telemedicina. Nível de evidência V: Opinião do especialista.

Descritores: Telemedicina. Ética Médica. Jurisprudência. Ortopedia.

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INTRODUCTION

Telemedicine and telehealth are both remote ways to offer medical care, but have different meanings. Telemedicine involves a real-time virtual interactivity between patient and physician. Otherwise, telehealth has a broad meaning and consists of use of communication technology to promote health care, medical education and health care center administration.¹

The first report of telemedicine was in the end of XIX century when electrocardiographic data was transmitted by telephone line. In 1927, the first video consultation occurred between patient and doctor.² The COVID-19 pandemic caused most ambulatory consultations to be cancelled, affecting thousands of patients around the world and forcing many countries to search for new strategies, such as telemedicine.³ Many studies show that patients have high satisfaction

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with telemedicine because it is easy to access, saves time, and reduces expenses - particularly among patients that need to travel long distances or participate in labor.⁴⁻⁶

In developed countries, telemedicine is consolidated with remote monitoring services of patients with chronic and acute diseases with large investments. In 2016, when the world did not even imagine a pandemic, the global telemedicine market was estimated to grow to US\$ 19.2 billion in 2014,35.1 billion in 2018, and 43.4 billion in 2019. The European market alone was expected to triple to 12.6 billion U.S. dollars in 2019. However, with the advent of the pandemic, the amounts invested in telemedicine vastly surpassed these previous estimations.⁷⁸

On the other hand, developing countries have less effort and investment in this area, likely due to lack of resources, return on investments, and technological infrastructure. However, telemedicine is an important ally to expand access to basic health services and bring the needy population closer to specialized centers located in large cities in developing countries.^{6,8}

Brazil is a continental country with many difficult access areas and has heterogeneous distribution of medical resources.⁷ At the beginning of the COVID-19 pandemic, the Brazilian ministry of Health regulated telemedicine actions to offer remote care and allowed basic unit of health to perform teleconsultations since ambulatory consultations had been cancelled.⁹

According to the World Health Organization (WHO), one of the major changes that will occur in the 21st century is the availability of high-quality healthcare for all. To achieve this, the WHO recommends that countries use telemedicine as a health planning strategy. However, despite the increased use of telemedicine, there are a large number of ethical and legal problems, which hinders the expansion of this modality of care.¹⁰

There is in current literature some information about the legal and ethical aspects of telemedicine, however the data is fragmented. This article aims to provide a general explanation about the ethical and legal aspects of telemedicine, with emphasis on telemedicine applied to orthopedics, known as tele orthopedic.

Telemedicine applied to orthopedic specialty

A study published in 1997 analyzed 410 virtual orthopedic consultations for 2 years with 43% of orthopedic consultations were fracture, 35 % ligamentous injury, joint swelling and infection and 18 % postoperative evaluation. No adverse effects were observed, and the authors concluded that tele orthopedic is an excellent option for performing diagnosis and follow-up examinations on orthopedic patients.¹¹

In 2017, an Australian publication evaluated 9 tele-orthopedics services and observed that was good to diagnose and follow-up fracture cases and performed successfully perioperative consultations.¹² Laskowsli et al, described musculoskeletal examination by telemedicine and showed that many physical tests are feasible by tele orthopedics, taking another step towards this form of teleconsultation becoming a reality.¹³ Jaenisch M et al. evaluated viability of virtual physical examinations of hip joints. They compared presential and virtual examinations and showed that there is good concordance in the inspection and follow-up on orthopedic surgical wounds.¹⁴ Polinski et al published a satisfaction survey in which 95 % of all patients were very satisfied with teleconsultation and be considered telemedicine equal or better than in-person consultation. Publications suggest that tele orthopedic is safe, cost-effective and high rates of satisfaction among patients.¹⁵ Pastora-Bernal JM et al showed that tele-rehabilitation had good results in patients after knee and hip arthroplasty.¹⁶

Altogether, these results indicate that orthopedic specialty works, via telemedicine, in several ways such as diagnosis, treatment

and rehabilitation. In addition to reducing costs, it is safe and increases the engagement of patients in treatment with potential to be explored.¹⁷

Ethical aspects of teleorthopedia

Despite of technology development and new models of care, the ethical foundations in the practice of medicine remains unchanged. Unlike traditional interaction, tele-orthopedics raises concerns about the risks to privacy and confidentiality, limitation of physical examination and the possible breakdown of the doctor-patient relationship.^{1,2} Telemedicine respects the ethical principles of universality, equity, and integrality, since it allows all patients access to the health system and enables consultations with highly specialized medical centers located in urban areas.^{4,18}

With the use of telemedicine, some doubts have arisen and one of them is what would be the effect of telecommunication problems on the patient. In other words, if issues such as connection problems, delay, poor image and audio quality and disconnection occur, anxiety and vulnerability in the patient may be caused or, perhaps, even damage.¹⁹ However, in general, the advantages of telemedicine clearly outweigh the disadvantages.^{1,20}

In October 1999, the 51st General Assembly of the World Medical Association, held in Tel Aviv, Israel, published the "Tel Aviv Declaration on Responsibilities and Ethical Norms in the Use of Telemedicine." The statement says, "Regardless of the telemedicine system under which the physician is operating, the principles of medical ethics which are globally binding upon the medical profession must never be compromised." The Tel Aviv Declaration emphasizes that because of the risks of information leakage inherent to some types of electronic communication, the physician has an active obligation to ensure that all established standards of security measures have been followed to protect the patient's confidentiality.

The absence of physical interaction between physician and patient may be a problem. Besides, quality level of telemedicine is difficult to define because of lack of regulations. Regarding the ethical aspects to maintain privacy and confidentiality, autonomy, beneficence, nonmaleficence, justice and equity must be respected in telemedicine and teleorthopedics.^{19,20}

Autonomy: The patient has the right to receive all information about the recommended treatment, both via tele orthopedic and by faceto-face consultation. Autonomy begins even before the consultation, explaining that the two modalities of care are available and clarifying that the patient has full autonomy to switch at any time, unless it violates the patient's safety or the physician's awareness.

Patient privacy and confidentiality should be respected in the same way as in face-to-face consultation and should not be shared without patient authorization. In addition, during tele orthopedic consultations, all people together with patient in the consultation should be identified and, likewise, all individuals with the physician should also be identified and remain in the consultation with the patient's permission.^{1,2,21} Despite the creation of protocols of care and orthopedic physical examination, such as the publications of Tanaka and Laskowsli, the patient needs to be informed about the limitation of tele orthopedics, such as the physical examination^{13,22} and advised, if necessary, that the physician could request his face-to-face evaluation.

Beneficence: The principle of beneficence is the ethical obligation to maximize benefit and minimize injury to the patient. As such, the medical professional must have the greatest technical information possible to ensure a beneficial medical act to the patient.

In tele orthopedics this principle occurs through medical education. It is not plausible to believe that physicians move from face-to-face to virtual care without prior training. Recent studies show that 75% of physicians feel uncomfortable in performing virtual consultations without previous experience in telemedicine and 95% in performing diagnosis and deciding treatment without physical evaluation.²³

Currently in Brazil, several orthopedics centers have huge queues of patients waiting for joint replacement. Many of these patients live far away from hospitals or have limitations of transportation. Tele orthopedics allows the care of these and other patients, avoiding long trips and waiting time, besides avoiding contagion by the new coronavirus.^{4, 24}

Nonmaleficience: It is the medical action of causing the least harm or no harm to the patient's health. It is associated with the maximum hippocratic *primum non nocere*, *i.e.*, first not harm. Telemedicine has several benefits, such as time savings, costs and environmental pollution.²⁴ However, telemedicine can present threats, such as the breakdown of patient autonomy, by imposing virtual care without the possibility of choice. Another situation is the choice of inadequate treatment, because of physician's inexperience with telemedicine or the low accuracy of the virtual physical examination. In order to avoid that, the physician should evaluate patient face-to-face in case of doubt diagnoses or any alarm signal.^{4, 21} In addition, recommendations for the use of electronic medical records and digital platforms in order to protect the privacy and confidentiality of the patient must be followed.

Justice and equity: The principle of justice has equity as its fundamental condition and treats each patient according to what is morally appropriate, providing to each individual what is due to them. Physicians should be impartial, and resources should be distributed fairly. Orthopedics, because it treats disorders of the musculoskeletal system, has patients with osteoarticular pain and movement restrictions. Thus, patients with difficulty in locomotion have the possibility of access to orthopedic services, via tele orthopedics, on par with face-to-face care.⁴

Table1 - Pros and cons of tele-orthopedics regarding to ethical aspects. (Table 1)

Legal aspects of tele orthopedic

Currently, telemedicine is being applied to several medical specialties, facilitating the treatment and follow-up of patients with access limitation. Tele orthopedics allows the provision of orthopedic care to patients regardless of distance. Besides, it has high patient satisfaction and allows greater effectiveness in rehabilitation after surgeries, as it reduces travelling time, waiting time and transport expenses.^{1, 25} Although the care is virtual, the legal aspects of telemedicine remain the same as in-person care.

Table 1. Pros and cons of tele-orthopedics regarding to ethical aspects.			
Ethical principles	Pros	Cons	
autonomy	Autonomy to choose care modality / Patient participates in decision making	Limitation of physical examination/Risks privacy and confidentiality	
Beneficence	Reduce travelling and waiting time, absenteeism on work, transportation expanses/ Consultation even in the COVID-19 pandemic	Internet access and technological equipment limitation	
Nonmaleficience	Autonomy/ Reduces travelling and waiting time, absenteeism on work, transportation expanses / Avoiding hospitals	Risk privacy and confidentiality /Interference and change of medical conduct	
Justice and equity	Allow access to patients with disability / Orthopedic care to risk group in the COVID-19 pandemic	Internet access and technological equipment limitation / Minimum patient's education degree	

Silva et al., studied 30 years of telemedicine policy in the SUS and identified 79 federal laws related to telemedicine and 31 resolutions of councils.²⁶ In 2002, 19 years ago, the Federal Council of Medicine published resolution n°.1,643/2002 that defines telemedicine as the exercise of medicine through audiovisual communication and data transmission, with the objective of health care, education, and research.

In 2017, the Federal Council of Medicine (FCM) report n°.14/2017 regulated the use of WhatsApp in a hospital environment, for communication between doctors and their patients, as well as between physicians.

In 2019, FCM resolution n°.2,227/2018 of February 6, 2019, defined telemedicine as a form of technology-mediated medical services. However, FCM resolution n°.2,228/2019 of March 6, 2019, revoked FCM resolution n°. 2,227/2018 and reestablished FCM resolution n°.1,643/2002. This fact occurred due to high number of proposals submitted by Brazilian physicians to change the terms of FCM resolution n°. 2.227/2018, since this resolution required prior establishment of a face-to-face consultation and, for a long time or chronic diseases, in-person consultation was recommended at intervals not exceeding 120 days.

On March 19, 2020, officio of FCM n°.1,756/2020 recognized that "as exceptionality and for as long as the battle to combat contagion of COVID-19 lasts, recognizing the possibility and effectiveness of the use of telemedicine, besides of the provisions in FCM resolution n°.1,643 of August 26, 2002". On April 15, 2020, law n°.13,989/2020 was published, which has authorized telemedicine during Coronavirus pandemic. In article 3, the practice is defined as "the exercise of medicine mediated by technologies for the purposes of care, research, disease and health promotion". Article 4 says "the physician must inform the patient of all limitations inherent in the use of telemedicine" and Article 5 " telemedicine service will follow rules and ethical aspects of face-to-face care".²⁷

Telemedicine and tele orthopedic must follow the rules of Civil Framework of the Internet ²⁸ and law n°.13,709 of August 14, 2018 -General Law for the Protection of Personal Data (GLPPD). In Article 1 of GLPPD, regards the processing of personal data, including in digital media, by a natural person or by a legal entity under public or private law, with the aim of protecting the fundamental rights of freedom and privacy and the free development of the personality of the natural person.²⁹

Regarding the legal aspects of medical practice in tele orthopedic, the informed consent form, medical license, digital platforms and prescription are important points to be discussed.

Informed consent: Following the principle of autonomy, the patient has the right to accept or not the consultation via tele orthopedic after explanation about the benefits and risks. The inform consent form is necessary because there is a medical intervention mediated by a technological resource. The absence of an informed consent form characterizes an infringement of medical ethics, except in confirmed situations of imminent danger of life. This consent should be prepared according to the changes in the doctor-patient relationship resulting from the intermediate of high-tech devices.

In addition, the Superior Court of Justice (SCJ) understands that the signing of the consent form removes the responsibility of the medical professional, if it is demonstrated that the eventual damages were due to factors unrelated to their performance, but the lack of the consent form leads the professional not to comply with the duty of information.

Medical license: According to the Code of Medical Ethics, for the practice of medicine, registration is required in the Regional Council of the respective state. On May 18, 2020, Regional Council of Medicine of Rio Grande do Sul published resolution n°.10 that says, "medical care via remote means provided directly to patients

located in another state or country can only be performed if the physician has enrollment in the Regional Council of Medicine of the state in which the patient is located as a way to ensure the continuity of care in person".

FCM, in order COJUR n°.383/2020, does not dispense secondary enrollment when there is the provision of services in states other than where the doctor has primary enrollment, even if through telemedicine.

Therefore, to attend to the patient from another state virtually, it is necessary to have the license in that state for the practice of medicine to be considered legal.

Digital platforms: The electronic medical records must have security guarantee level 2 (SGL2) established in the Certification Manual for Electronic Health Registration Systems of the Brazilian Society of Health Informatics - Federal Council of Medicine (SBIS-CFM), digital certificate, computer with microphone, webcam and internet access and an audio and video platform that is compatible with Health Insurance *Portability and Accountability Act* (HIPAA).³⁰

Prescription and digital certificates: The one proven by law n°.13.989/2020, the medical prescription and medical certificate can be sent in digital format by e-mail or by application of message to the patient. For this, it is necessary use of electronic signature through certificates and keys issued by the Brazilian Public Key Infrastructure- ICP-Brazil. The Pharmacy Council clarified that the prescriptions must contain a digital signature with ICP-Brazil certificate, i.e., digitalized copies of manually issued prescriptions, as photos or scanned files are not recognized by Anvisa.

Medical responsibility: The physician who performs care, via telemedicine, has the same responsibilities over the patient as the physician in face-to-face care. Currently, there is little discussion about the alterations and the result of doctor-patient relationship by telemedicine.^{1,20,31}

Even with the patient's informed consent, physicians who provide care through tele orthopedic are responsible for possible harm to the patient. There is concern regarding the fact that the misdiagnosis and mistreatment are associated with the absence of presential physical examination, as article 37 of the Code of Medical Ethics states that: "Prescribe treatment and other procedures without direct examination of the patient, except in cases of urgency or emergency and proven impossibility of performing it, in which case, should do so immediately after the end of the impediment, as well as consult, diagnose or prescribe by any way of mass communication". Thus, as stated in Art. 4 of law n°. 13.989/2020: "The physician must inform the patient of all the limitations inherent to the use of telemedicine, since of the impossibility of performing physical examination during the consultation". In addition to ethical norms, the physician is also subject to civil and legal sanctions, as is law n°.13,989/2020 in article 5: "the provision of the telemedicine service will follow the common normative and ethical standards of face-to-face care".27

Patient responsibility: In tele orthopedic, as in telemedicine, the patient also has responsibilities, especially regarding sending exams, clinical information and data transmission. For example, in case of failure of connection by the patient during important guidance on treatment or if incomplete or erroneous information about the clinical condition is provided.^{1, 23} (Table 2)

FINAL CONSIDERATIONS

The emergence of the COVID-19 pandemic expanded the use of telemedicine, which generated discussion of ethical and legal aspects on this subject. Telemedicine care differs from faceto-face care and requires physicians to be trained to perform this type of care. As medical graduation has poor contact with telemedicine, physicians feel uncomfortable in performing a
 Table 2. FCM and Federal Government relevant issues to telemedicine since 2002.

Issues	Entity	Contents
Resolution No. 1,643/2002	FCM	Define and discipline provision of services via Telemedicine
Resolution No. 1890/2009	FCM	Define tele-radiology
Ordinance No. 35/2007	Fed. Government	National Program of Tele health
Ordinance No. 402/2010	Fed. Government	Tele health in Family Health Strategy - SUS and repeal ordinance 35/2007
Ordinance No. 2,546/2011	Fed. Government	Redefine and expand Brazil Tele health Program and repeal ordinance 402/2010
Opinion No 09/12	FCM	Videoconference in administrative legal consultation
Order SEJUR nº 194/2013	FCM	Guidance on how to proceed to enable legal consultation by videoconference
Resolution No. 2,107/2014	FCM	Define tele-radiology and repeal Res. FCM No. 1,890/09
Law No. 12,965/2014	Fed. Government	Internet civil landmark
Resolution No. 2,178/2017	FCM	Regulate medical apps
Opinion No 14/2017	FCM	WhatsApp regulamentation
Opinion No 17/2018	CFM	O aconselhamento genético por telemedicina.
Resolução nº 2.227/2018	FCM	Define and discipline telemedicine. Repeals Res.CFM No. 1643/2002
Law No. 13,709/2018	Fed. Government	General Law for the Protection of Personal Data
Resolution No. 2,264/2019	FCM	Discipline to telepathology
Resolution No. 2,228/2019	FCM	Discipline telemedicine, reestablishe Res.CFM no. 1,643/2002
Opinion No 3/2020	FCM	Prohibit legal consultation without in-person examination
Opinion No 8/2020	FCM	Prohibit occupational examinations without direct clinical examination on the worker
Opinion No 10/2020	FCM	Prohibit legal consultation without examination of the patient
Order COJUR Nº 383 /2020	FCM	Not authorize the waiver of secondary enrollment in another state, even via telemedicine
Offício Nº 1756/2020	FCM	Recognize telemedicine for as long as the pandemic lasts
Law 13.989/2020	Fed. Government	Allow telemedicine for the duration of the pandemic

teleconsultation. In addition, the lack of a public policy in Brazil hinders the implementation of telemedicine and guidance of health professionals. However, regardless of the modality, the ethical principles of autonomy, beneficence, nonmaleficience and justice must be respected in the same way as privacy and confidentiality of patient data. Moreover, the requirement for regulation of telemedicine in a short period of time did not allow time for adequate discussions on the matter, generating numerous publications of resolutions and laws, some of which were divergent and outdated.

Currently, telemedicine is regulated by law n°.13.989/2020 that authorizes telemedicine for the duration of the Coronavirus pandemic. However, this modality of care is already consolidated and, even with the increase in vaccination around the world, it will tend to be increasingly used, both for care and for research.

Telemedicine applied to orthopedics, known as tele orthopedic, has an extensive field of activity from diagnosis to rehabilitation, with low risk, high patient satisfaction and is an expanding area with potential to be studied. The continuous implementation of tele orthopedic is changing the form of care and has numerous advantages. However, like any intervention, there are risks that should be calculated and made available to the patient. In addition, medical training and development of protocols in telemedicine contributes to a better care.

Thus, orthopedists during tele orthopedic should be guided by the traditional moral and ethical precepts of in-person care but must also adapt to the legal bases of telemedicine.

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