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LAWSUITS AFTER DERMAL FILLER INJECTION REGISTERED IN THE STATE COURT OF SÃO PAULO, BRAZIL

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Abstract

The search for aesthetic procedures in the health sector have increased in the last years. The increase in the number of procedures brought together a higher number of lawsuits, especially when it comes to the injection of dermal fillers. This study aimed to revisit the jurisprudence of the State Court of São Paulo, Brazil, to investigate the risk factors behind the lawsuits and convictions of health care professionals after the injection of dermal fillers. The sample consisted of 46 lawsuits published between 2000 and 2022 in the State Court of São Paulo, Brazil. Data extracted from each lawsuit were: the year of publication, the reason behind the lawsuit, the defendant (individual or legal entity), sex of the plaintiff, type of dermal filler, whether there was a technical legal/forensic examination of the case and conviction. Most of the lawsuits were published between 2020 and 2022 (n = 26, 56.52%). The presence of intercurrences was the most common reason behind the lawsuits (n = 27, 58.69%). The defendants were mostly health care providers (n = 16, 34.78%), individually, and their combination with legal entities (n = 16, 34.78%), separately (the rest was legal entities alone). Female plaintiffs were predominant (n = 36, 78.26%), as well as the use of hyaluronic acid as dermal filler (n = 35, 76.08%). Technical legal/forensic examination was registered in 34 lawsuits (73.91%). Most of the defendants were convicted (n = 25, 54.34%). The chance of conviction was 3,9 times higher if the case was judged between 2017-2019 compared to 2020-2022 (p = 0.05); and 3,4 times higher if the case was based on intercurrences (p = 0.05). It is estimated that convictions in lawsuits after dermal filler injections might decrease in more recent cases. However, higher chances of conviction might be expected in the presence of intercurrences (e.g. accidents or complications) in the State São Paulo, Brazil.

Keywords: Aesthetics. Dermal fillers. Forensic Dentistry. Jurisprudence. Law. Medicine.

1. Introduction

Over 10 million non-invasive aesthetic procedures were performed in 2020 – an increase of 24.1% compared to 2016 (ISAPS 2020). Botulinum toxin and hyaluronic acid have been the most common products among those used in injectable procedures (ISAPS 2020). Brazil was ranked #3 for this type of procedure in 2020 (ISAPS 2020).

The search for aesthetic procedures is not only justified by the need to age better, but also because people want to improve their features (Spirduso 2005), especially in the face. Facial dermal fillers are popular products when it comes to corrections of skin aging and proportions (Akinbiyi et al. 2020). These products are classified as temporary and permanent ones (Carruthers et al. 2015). The former are absorbable and because of this property their injection can be reversible. Temporary dermal fillers can be absorbed by the organism with time, or through induced enzymatic degradation (Guidoni et al. 2019). On the other hand, permanent dermal fillers may offer long lasting results, but their management is more complex since they require surgical removal in case of intercurrences (Salles et al. 2008).

Among the temporary dermal fillers, the hyaluronic acid (HA) is the most popular since the product was firstly approved by the Food and Drug Administration (FDA), in 2003. HA include may increase volume (Guidoni et al. 2019) and promote a better contour (Balassiano and Bravo 2014) of anatomic regions of the face. Moreover, HA is present in the human extracellular matrix, and consequently it is biocompatible (Daher et al. 2020). On the other side of the spectrum, there is polymethylmethacrylate (PMMA) – a permanent dermal filler approved by the Brazilian National Health Surveillance Agency (ANVISA), in 2007. This product was more popular in the years that followed its approval, but nowadays it is not so common because of the required surgical corrections (Badin 2005; Ferneini and Ferneini 2016).

By the year 2014, only physicians were allowed to perform aesthetic procedures with dermal fillers in Brazil. After 2014, the Brazilian Federal Councils of Biomedical Sciences (via document CFBM 241/2014), Pharmacy (via document CFF 616/2015), Nursery (via document COFEN 0529/2016) and Dentistry (via document CFO 176/2016) released official administrative communications to gain rights over the application of injectable fillers. The increasing number of health care professionals performing treatments with injectable dermal fillers combined with the recent popularization of aesthetic procedures on the face could justify an increase in the number of lawsuits.

In the health sector, lawsuits are started to investigate the potential breach of duty, causation, and the damage to a patient. If the claimed situation is confirmed, a conviction is established to enable a compensation to the plaintiff (Dal Poz 2020). Lawsuits can be established against the health care professional, individually, against the clinic (legal entity), or both. Each of these cases will require a different assessment of professional liability. Screening the jurisprudence regarding health sector lawsuit should be preferably performed in large databases. The State Court of São Paulo is the currently largest database of lawsuits in Brazil.

In this context, the present study aimed to revisit the lawsuits registered in the first and second instances of the State Court of São Paulo, Brazil, to investigate the risk factors behind the convictions of health care professionals after the injection of dermal fillers.

2. Material and Methods

This study was performed with ethical clearance from the institutional committee of ethics in human research. The study model was observational analytical cross-sectional. The methodological strategy designed for this study was based on the search of secondary data from an existing judicial database. The study model followed the structure of previous literature (Franco et al. 2012; Picoli et al. 2020).

The sample consisted of lawsuits judged at the State Court of São Paulo, Brazil. The inclusion criteria were lawsuits published between 2000 and 2022, lawsuits established by a patient against health care professional(s) in the civil Court, judged in first or second instances, and regarding claims of injectable dermal fillers. It is worth explaining that lawsuits judged in first instances are based on the decision of a single Judge. Appeals will move the case from the first instance to the second. In the second instance, lawsuits are judged by a group of Judges. The exclusion criteria were cases of dermal fillers that were not injected in the face, cases that were not electronically available open access, patients that were treated with injectable dermal fillers other than HA and PMMA, and cases that were not established based on professional liability.

The database of the State Court of São Paulo (https://www.tjsp.jus.br/) was searched up to July/2022 with the following keywords: hyaluronic acid, polymethylmethacrylate, error, complication,

necrosis, and facial harmonization combined with the Boolean operators AND & OR. The search was fully online and was performed by a Forensic Odontologist (FO) with 6 years of experience supervised by another FO with 11 years of experience.

Sample selection was performed in two steps: 1) reading of the lawsuit's summary. In this phase exclusion criteria were applied. If the summary of the lawsuit was missing, the full-text was saved for the next phase; 2) full-text reading was performed to assess the eligibility of the lawsuit and allow data extraction. Data to be extracted were a) the year of publication of the lawsuit, b) the reason behind the lawsuit, c) the defendant (individual or legal entity), d) sex of the plaintiff, e) type of dermal filler, f) whether there was a technical legal/forensic examination of the case, g) whether there was a conviction, and h) the amount of compensation.

Data were analyzed descriptively by means of values of central tendency (mean) and dispersion (standard deviation) for continuous variables. Categorical variables were assessed by counting the absolute (n) and relative (%) frequencies of data distribution. Next, the potential factors associated with the outcome "conviction" were investigated. Odds ratio and their respective 95% confidence interval were calculated for each variable considered as a potential risk factor for association with the conviction of the health care professional. All the analyses were performed with Stata 17.0 software package (StataCorp LLC, College Station, TX, USA) considering a significance level of 5%.

3. Results

The initial search resulted in 155 lawsuits (118 in first instance and 37 in second instance). Three studies were excluded because they were not established in the civil Court, five were not based on professional liability, thirty-eight were not cases of HA or PMMA injection, twenty-six were duplicates found within the first and second instances, separately (using different keywords), thirty-seven lawsuits were duplicates between the first and second instances – as consequence of an appeal of the initial decision. From the eligible 46 lawsuits (thirty were from first instance and sixteen were from second instance). In the second phase, full texts of lawsuits were read, but no exclusions were performed.

The first lawsuit of the sample was published in 2014. Most of the lawsuits were published between 2020 and 2022 (56.52%). The most prevalent reason behind the lawsuits was the presence of intercurrences after the injectable dermal filler (n = 27, 58.69%), followed by aesthetic dissatisfaction (n = 19, 41.30%) (Table 1). Examples of intercurrences were: necrosis (n = 8), local infection (n = 7), late immune reaction (n = 4), edema (n = 2), blindness (n = 2), nodules (n = 1), facial paralysis (n = 1), ecchymosis, edema and nodules (n = 1), and facial cellulitis (n = 1) (Figure 1).

Table 1. Absolute (n) and relative (%) frequencies of the lawsuits judged in the first and second instances and their characteristics.

Characteristics of the lawsuits	1st instance		2nd instance	
	n	%	n	%
Year of publication				
2014-2016	6	20.0	3	18.8
2017-2019	7	23.3	4	25.0
2020-2022	17	56.7	9	56.3
Reason behind the lawsuit				
Aesthetic dissatisfaction	12	40	7	43.8
Intercurrence	18	60	9	56.2
Defendant				
Individual health professional	9	30	7	43.8
Legal entity	12	40	2	12.4
Combined	9	30	7	43.8
Sex of the plaintiff				
Female	23	76.7	13	86.7
Male	7	23.3	2	13.3

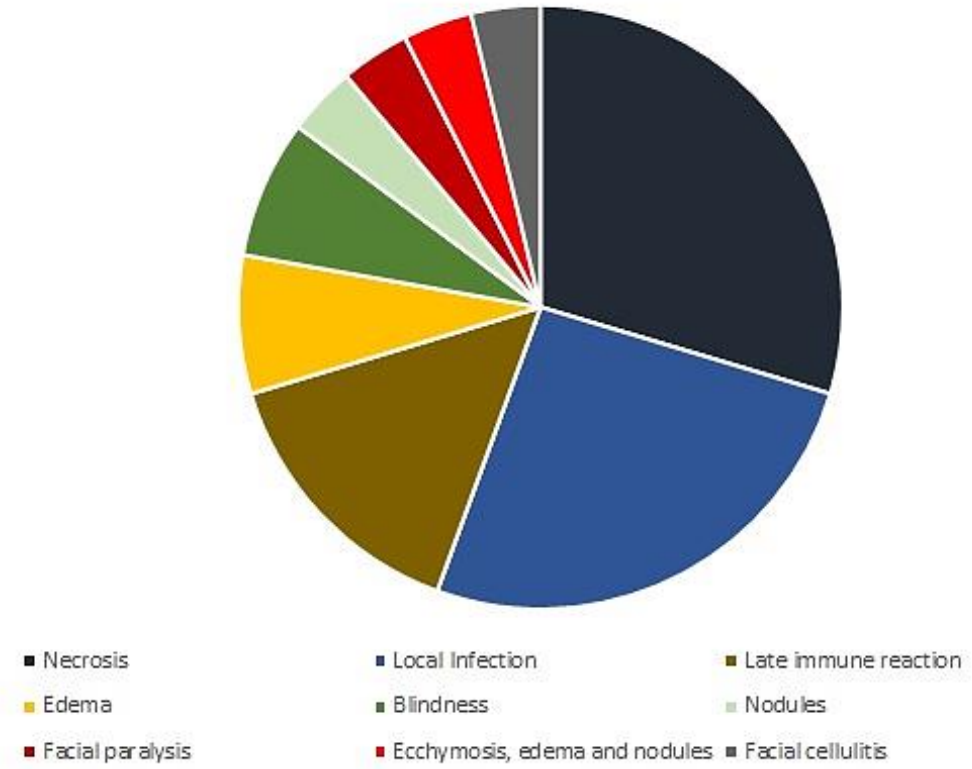

Figure 1. Types of intercurrences and their distribution detected in the present study among the eligible lawsuits.

The defendants were mostly health care providers (n = 16, 34.78%), individually, and health care providers combined with legal entities (n = 16, 34.78%). The remaining amount consisted of legal entities alone (Table 1). When health care providers were suited alone, most of them were physicians (n = 13, 81.25%), and dentists (n = 3, 18.75%). When legal entities were suited alone, they were mostly medical clinics (n = 6, 46.15%) aesthetic clinics (n = 5, 38.46%) and dental clinics (n = 2, 15.38%). The combinations of individual health care providers and legal entities were physician and medical clinics (n = 11, 64.70%), dentists and dental clinics (n = 1, 5.88%), aesthetic clinics and dentist (n = 1, 5.88%), aesthetic clinics and pharmacist (n = 2, 11.76%), and physiotherapy clinics and physiotherapist (n = 1, 5.88%). The was a single case combining a physician and a health insurance company. The female sex was predominant (n = 36, 78.26%) among the plaintiffs (Table 1).

HA was used in 35 out of 46 cases (76.08%), while PMMA was used in 11 cases (23.92%). Technical legal/forensic examination was performed in 34 cases out of 46 (73.91%) – in all the cases, the legal/forensic expert was a physician (Table 2). Convictions were predominant in the first instance (60%), but not in the second instance (Table 2). All the compensations were below that requested by the plaintiffs. The highest amount requested was about USD 312.529,27 (R$1.674.000,00 – Brazilian currency), while the lowest amount was USD 410,73 (R$2.200,00 – Brazilian currency) (Table 3).

Table 2. Absolute (n) and relative (%) frequencies of the lawsuits judged in the first and second instances regarding the case-specific characteristics of injectable dermal fillers.

Characteristics of the lawsuits	1st instance		2nd instance	
	n	%	n	%
Product				
HA	23	76.7	13	86.7
PMMA	7	23.3	2	13.3
Technical legal/forensic examination				
Performed	22	73.3	12	75.0
Not performed	8	26.7	4	25.0
Decision				
Convicted	18	60	7	43.8
Acquitted	12	40	9	56.2

HA: hyaluronic acid; PMMA: polymethylmethacrylate.

Table 3. Measures of central tendency and dispersion of the amount of compensation claimed and paid to the plaintiffs.

Compensation	1st instance		2nd instance	
	Mean	SD	Mean	SD
Amount claimed	R$127.788,10	R$268.763,50	R$82.474,11	R$111.737,90
Amount paid	R$12.649,86	R$35.639,75	R$13.354,85	R$17.927,04

SD: standard deviation.

Odds ratio revealed that chances of conviction were 3,9 times higher in cases judged between 2017 and 2019, compared to the cases between 2020 and 2022 (p = 0.05). Chances of conviction were 3,4 higher if the cases were based on the claim of intercurrence (p = 0.05). Male plaintiffs had a lower chance (68% less) of compensation compared to female plaintiffs (p = 0.15). The chance of conviction was twice higher in the presence of technical legal/forensic examination (p = 0.31) (Table 4).

Table 4. Associations between variables that could represent risk factors for convictions in lawsuits that involve cases of injectable dermal fillers.

Variable	OR	CI95%	*p*
Instance			0.30
1st	1.00		
2nd	0.52	0.15;1.77	
Year of publication			0.05
2014-2016	0.24	0.04;1.41	
2017-2019	3.86	0.69;21.43	
2020-2022	1.00		
Reason behind the lawsuit			0.05
Aesthetic dissatisfaction	1.00		
Intercurrence	3.43	1.00;11.7	
Defendant			0.19
Individual health professional	0.24	0.05;1.12	
Legal entity	1.00		
Combined	0.51	0.11;2.36	
Sex of the plaintiff			0.15
Female	1.00		
Male	0.32	0.68;1.48	
Product			0.99
HA	1.00		
PMMA	1.01	0.26;3.94	
Technical legal/forensic examination			0.31
Performed	1.00		
Not performed	2.00	0.53;7.60	

OR: odd ratio; CI: confidence interval; p: significance level set at 5%.

4. Discussion

Aesthetic treatments involve patient's expectations, and when the expected outcomes are not met, judicial disputes may arise. This study aimed to contribute to the current scientific literature with knowledge to understand potential risk factors that could be associated with the conviction of health care professionals after the injection of dermal fillers.

Data extracted from the lawsuits at the State Court of São Paulo, Brazil, showed that records were registered between 2014 and 2022 (despite the search starting from 2000). This phenomenon can be justified by the fact that the State Court is running with digital files since 2015 and our search was performed solely electronically. Most of the lawsuits (22 out of 46) were published between 2020 and 2022, which is explained by the administrative authorization of health care entities that enabled the injection of dermal fillers by health professionals other than physicians. It must be noted that the Brazilian Consumer Code establishes the time of five years to file a suit once the problem/damage in a product/service is detected. Moreover, the average time of a lawsuit in Brazil is about three years (Brasil 2022). These time values should be considered to understand the tendency of finding more lawsuits over the time.

Similarly, with the update of this study in the upcoming years, it should be normally expected an increasing number of male plaintiffs. The current outcomes revealed the predominance of females as plaintiffs (78.26%), and this is probably because of the tradition and culture of women taking care of health and beauty. Despite these outcomes, future lawsuits should present an increasing number of males as

well, especially because the male beauty market has grown in the last decade and males started searching for facial aesthetics more often (American Society of Plastic Surgeons 2018).

When it comes to the reason behind the lawsuit, two main types of claims were detected: one based on aesthetic dissatisfaction and another based on intercurrences. Aesthetic dissatisfaction (41.30%) is a subjective claim that relies on the perception of plaintiff's own beauty. The illustrate this phenomenon it is possible to observe that only six lawsuits (31.57%) based on aesthetic dissatisfaction were judged as aesthetic damage. This is to say that patients/plaintiffs may expect for outcomes that are not reachable. Managing patient's expectations and the potential outcomes of the treatment is only optimal if guided by an informed consent. Information about the treatment could be verbal, but should be preferably documented (Jones 2006; Bailey et al. 2011) to guarantee that the patient was provided with the autonomy to decide about a procedure, especially an aesthetic one. Additionally, patients frequently combine their frustrations with the treatment, such as the lack of cordiality, supervision or even care from the professional's side during the treatment. Understanding the patient's mind and foreseeing expectations with the treatment is minimizing the risk of judicial disputes. A lawsuit that is based on an intercurrence, in its turn, may have a more solid representation of the damage. In most of these claims, the lack of skill and knowledge from the professional's side can be considered malpractice (Crocco et al. 2012). Some of these intercurrences may require advanced (re)treatment, hospitalization, and complex surgeries (De Castro et al. 2007; Fadanelli et al. 2007). In this context, about 56.6% of the cases based on intercurrences (eventually malpractice) were confirmed as cases of damage to the plaintiff. Moreover, the plaintiffs were not only affected by the lack of an aesthetic outcomes but also experienced pain and sequels from the treatment.

The defendants involved in the lawsuits of the present study had a balanced distribution between individual health care professionals (n = 16), legal entities (n = 14) and the combination of both (n = 16). Most of the individual health care professionals suited were physicians, followed by dentists. This finding can be explained by the fact that physicians have performed aesthetic injectable procedure for a longer time compared to the other health care professionals. Studies such as the one from Picoli et al. (2020) have found different outcomes. With a sample of lawsuits in the field of orthodontics, the authors found a predominance of defendants that were individual health care professionals. The difference may rely on the fact that physicians that work with dermal fillers are usually dermatologists or plastic surgeons, and these professionals normally have their practice associated with health centers (legal entities). Health care professionals must be aware of the fact that aesthetic procedures are usually interpreted and judged in Court as an obligation of outcome/result. This type of obligation indicates that the expected outcome of the treatment must be achieved by the professional once the treatment is concluded. In this context, the professional and patients must have their expectations well-aligned before the treatment starts. Clarification and registration of the potential outcomes are necessary, especially by means of informed consent forms. Interestingly, most of the claims based on aesthetic dissatisfaction led to the acquittance of the defendant (63.15%). This phenomenon may be justified by the proper documentation and explanation of the treatment and potential aesthetic outcomes. Claims based on intercurrences, on the other hand, had a higher chance of conviction (>3.4 times). The outcomes were not statistically significant ($p = 0.05$) but had an important clinical significance. Based on these findings, we might highlight the relevance of proper documentation) to avoid claims based on aesthetic dissatisfaction and the obligation of results) and technical skills (to avoid claims based on intercurrences).

The presence of a formal technical legal/forensic examination was another topic of interest investigated in the present study. This is an important component of judicial procedures. The forensic examination aims to translate technical evidence into intelligible terms to a legal audience (Leal and Milagres 2012). In agreement with the existing literature (Franco et al. 2012), most of the lawsuits were examined by an expert; and in most cases the expert pointed out by the Court was a physician – which is expected given the predominance of lawsuits against physicians. It must be noted that the qualification of the expert does not necessarily must be the same of the defendant but should meet the requirements to properly explain the case and evidence to the Judge/Court. For instance, a physician may be named expert in a case in which a dentist is suited. Expert's report does not need necessarily to be accepted by the Judge but may contribute to the process of understanding the case.

Future studies should be designed to follow-up the jurisprudence of lawsuits after injectable dermal fillers in Brazil. Our outcomes indicate that the number of cases might increase in the upcoming years as a result of the increasing number of professionals that are allowed to perform these procedures in their practice. Additionally, because of the continental size of Brazil, more State Courts should be assessed to enable a better panorama of the lawsuits in the country.

5. Conclusions

Injectable dermal fillers led to an average prevalence of five civil lawsuits per years judged in the State Court of São Paulo, Brazil. Convictions were predominant when the lawsuit was based on alleged intercurrences. More specifically, the presence of intercurrences tripled the chances of conviction. Among the several health care professionals suited between 2014 and 2022, physicians were the most common, followed by dentists. Technical legal/forensic examination was performed in most of the cases, and mostly by physicians. The amount of compensation established by the Court was always lower than the amount initially claimed by the plaintiffs.

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