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MEDICO-LEGAL EVALUATION OF KELOID FORMATION FOLLOWING PROMINENT EAR CORRECTION: MALPRACTICE OR COMPLICATION?

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Abstract: Prominent ears (=prominauris=) are anatomical auricular deformities that are seen in 5% of the population, are autosomal dominant in the white population, and have psychological negative effects, especially on young girls and boys in their social environments. Various surgical intervention methods have been defined and applied for the treatment of prominent ears. After these surgical interventions, some undesirable results may occur, one of which is hypertrophic scarring and keloid formation.

In the case of the 42-year-old female presented in this article, a lawsuit was filed against the physician and the hospital alleging medical malpractice after excessive keloid formation following prominent ear correction. The case was evaluated in medical and medico-legal aspects, and it was decided that the undesirable outcome was a complication, contrary to the usual legal decisions in Turkey.

As a result, it was thought that the establishment of a specific insurance system for the patient before surgical interventions will not only protect the patient in the event of an undesired outcome, but also reduce unfounded malpractice claims.

Keywords: prominent ear, otoplasty, keloid formation, complication, medical malpractice.

INTRODUCTION

Prominent ears (=prominauris=) are anatomic auricular deformities that are seen in 5% of the population, are autosomal dominant in the white population, and have psychological negative effects, especially on young girls and boys in their social environments [1-4].

Numerous techniques have been described for the correction of prominent ears, generally involving cartilage preservation and cartilage cutting. Furnas reported that one of the first otoplasty operations for the treatment of prominent ears was performed by Morestin in 1903 by removing a cartilage ellipse from the base of the conchal auricle, and subsequently, new otoplasty techniques were developed by Luckett in 1910, then by Mustarde and Stenstrom in 1963 [5]. In 1968, Furnas described otoplasty with the technique of using permanent sutures on the concomastoid to position the concha to the mastoid to correct the deformity of prominauris [1,5]. In 1995, Fritsch and Peeled described "incisionless otoplasty techniques" developed by themselves [6,7]. Today, these techniques or their modifications are used by many surgeons. It has also been stated that surgical methods other than otoplasty are preferred in some patient groups [2].

In previous studies, the rates of undesirable clinical conditions developing after ear correction surgeries have been reported as follows: 1.2%-60% postoperative pain and hypersensitivity, 0-16% bleeding, hematoma, wound healing and suture related problems, 0-10% infection, 0%-8.3% scarring, 0%-9% asymmetry, and 0%-30.8% revision surgeries/recurrence [2,8-10]. Hypertrophic scar or keloid formation, especially after postauricular incision, often causes patients to require more aesthetic correction operations after surgery [2,11].

Although there are articles in the literature that

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have evaluated the clinical aspects of prominent ear correction operations in detail, there is no article in the literature that has evaluated the medico-legal aspect of this issue.

The aim of this paper was to discuss the medico-legal dimension of hypertrophic scar and keloid formation following prominent ear correction operation based on the current case.

CASE

A 42-year-old female patient presented at a private hospital 8 years previously for prominent ear correction operation. Following the first otoplasty operation, pain and hypersensitivity developed in both auricles, bleeding from the sutures located behind the auricles in the following two days and swelling in the ears after about 45 days. The patient's coagulation functions before the operation were within normal ranges. Hemostasis was achieved by cauterizing the bleeding vessels during the operation. Care of the patient during the postoperative period in hospital and post-hospitalization follow-up examinations were carried out regularly. Initially, the healing status of the incision was normal. Sutures at the incision site were removed after seven days. There was no postoperative infection in the incision site. During a period of 5 months postoperatively keloid growth occurred, and so 5 months after the first operation, the patient was operated on again by the same surgeon because of keloid formation, but the postoperative keloid formation continued to increase in size. The defect area was primarily sutured and repaired after the keloid was excised and removed. After the keloid surgery, intralesional triamcinolone injections were administered once a month (three times in total).

The patient started a court case to sue the surgeon and the private hospital for compensation, claiming that "the operating surgeon did not comply with the standards of care". At 1.5 years after the first operation, the patient was referred by the court to our expert committee consisting of forensic medicine experts and plastic and reconstructive surgeons, to determine whether the situation which had developed was a complication or medical malpractice.

In the examination of patient, excessive keloid formation was detected in both auricles (Fig. 1 -Informed consent was obtained from the patient so that these images could be used in the article). In the review of the informed consent form, it was determined that in the preoperative explanations the patient was given sufficient information about the hypertrophic scar and keloid formation that may develop.

In the scientific evaluation supported by the literature, it was decided that the development of hypertrophic scar and keloid formation is an undesirable outcome, which is relatively independent of the method preferred by the surgeon and the procedure applied, and cannot be prevented by the surgeon. Considering that the patient was sufficiently informed before the first operation about the adverse conditions that may develop, the forensic medicine report stated that the result was a complication and thus it was presented to the court that the physician was not at fault in the occurrence of this undesirable outcome.

DISCUSSION

Keloid disease, characterized by hypertrophic scarring and excessive keloid formation, is defined as a benign, but locally aggressive and recurrent cutaneous fibroproliferative condition, which almost always occurs following trauma to the epidermis and dermis [12]. Although the pathogenesis of this extreme

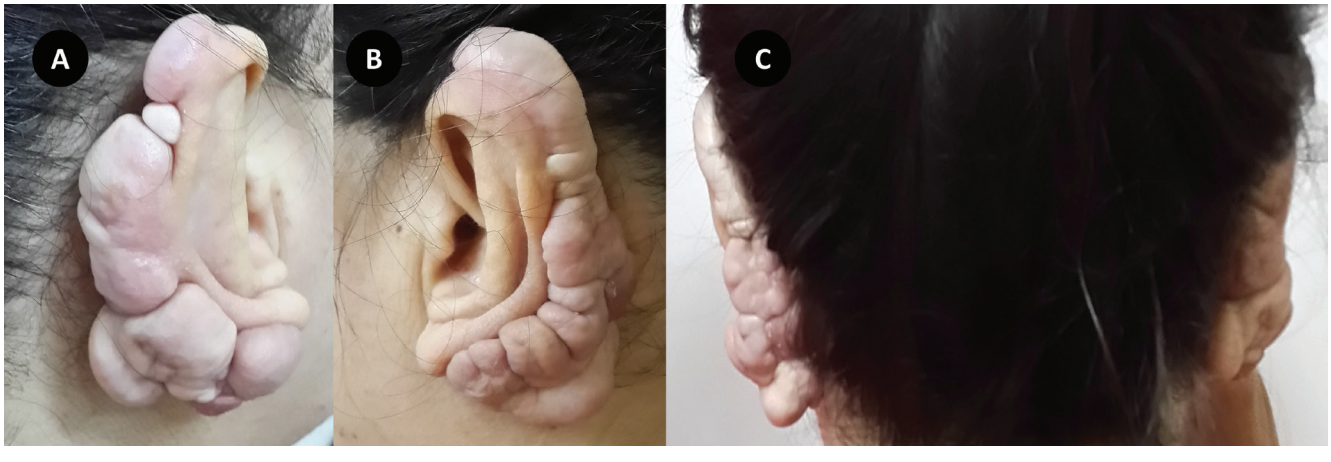

Figure 1. Side views of excessive keloid formation in (A) right ear, (B) left ear; (C) posterior view of excessive keloid formation in both ears.

hypertrophic scar formation and keloid formation has not been fully elucidated, it has been stated that normal wound healing mechanisms represent an abnormality, [12,13] and they can be seen in individuals of both sexes, all ages, and all ethnicities [12,14]. In a study which compared suture-based techniques with cartilage manipulation techniques, it was stated that the suture-based techniques used in the current case had a statistically significantly higher revision surgery/relapse rate [2]. However, the patient was informed about both techniques and their complications, and patient consent was obtained 24 hours before the operation in accordance with legal procedures.

In cases of medical malpractice, the physician can be punished according to the criminal law, can pay compensation according to civil law, and a disciplinary penalty can be given by the administration and the medical chambers. In the United States, medical malpractice law was derived from English common law and was developed by rulings in various state courts. Physicians in cases of alleged malpractice are judged within the framework of the common law in England, Wales, and the other Commonwealth countries exported during the time of the British Empire [15]. There is no specific legal regulation regarding "medical malpractice" in Turkey. Compensation lawsuits on this subject are conducted in accordance with the provisions of the Turkish Code of Obligations, which was revised in 2011 and includes the resolution of commercial disputes. The contracts signed by a physician or dentist working privately or performing surgeries in a public hospital for performing medical procedures such as aesthetic surgery or prosthesis application with the patient are considered within the scope of the artwork contract. Within the scope of this contract, the surgeon undertakes to act in accordance with the professional and technical rules required by a prudent contractor undertaking works in a similar field and to deliver the work without any defects. In the event of an undesirable result, the defect situation is determined by an expert examination [16]. According to the customary judicial practices in Turkey, the Supreme Court considers aesthetic surgeries for "beautification" purposes such as rhinoplasty, auricular correction, abdominoplasty, liposuction, breast reduction-augmentation-lifting, and hair transplantation within the scope of work contracts. In the five-year period of 2012-2016 in Italy, 101 of 144 malpractice cases related to plastic surgery resulted in compensation convictions [17].

Although no criminal case was proven in this study, in criminal cases filed with the allegation of medical malpractice, provisions against "injury" crimes within the scope of the Turkish Penal Code can be applied to physicians, depending on the presence of intent or negligence and fault. Injuries that leave a permanent scar on a person's face or cause permanent disfigurement to the face are defined as aggravating circumstances in Articles 87 1/c and 2/d of the Turkish Penal Code [18]. However, facial injuries causing permanent scars or disfigurement are considered aggravating factors in India, Italy, and some states of the United States [19]. In criminal suits in Turkey filed with the allegation of medical malpractice, it is defined as an act that will require punishment if the physician is not able to show the standard care and skills in his/her profession and causes an undesirable situation.16 Standard care is defined as "the care needed for a medical doctor who has the same situations and the same working conditions in consideration of the scientific and technique developing level of medicine science, working conditions, and educational level of a medical doctor" [20].

In the 10-year period between 208-2017 in Brazil, 80 of the 233 investigations opened and concluded against plastic surgeons were concluded in favor of the surgeon, 133 surgeons were given disciplinary punishments and 20 surgeons were dismissed [21].

Reis *et al*. recommended that reconstructive and plastic surgeons who have just started their profession make use of simulators with the same size and shape as the human ear in order to prevent procedural malpractices in otoplasty operations [22]. One of the most important reasons for patients to file a medical malpractice lawsuit is the inadequate surgical informed consent process. It was stated that 6%-10% of the cases filed with the claim of malpractice and applications to the medical disciplinary committee in the Netherlands were related to the insufficient surgical informed consent process, and in 20%-25% of these the process was concluded in favor of the complainant [23]. According to the patient rights regulation, it should be explained to the patient by whom, where and how the medical intervention will be performed, the estimated duration of the medical intervention, other treatment options, the benefits and risks of these options, the possible effects of the medical intervention on the patient's health, and possible complications. This information should be given a reasonable time before the operation [16]. Newell emphasized that the surgeon should be careful during the process of obtaining informed consent from patients who will undergo

plastic surgery, because body dysmorphic disorder (a psychological disorder in which a person becomes obsessed with imaginary defects in their appearance) and an addiction to plastic surgery impede cognitive competency and cause invalid informed consent [24].

As a result of the scientific evaluation supported by the literature, it was decided in the current case that the development of hypertrophic scar and keloid formation is an undesirable outcome, which is relatively independent of the method preferred by the surgeon and the procedure applied, and cannot be prevented by the surgeon; No behavior contrary to the standard of care was detected in the surgeon's behaviors before and during the operation, in the follow-up of the patient in the post-operative hospitalization and after discharge. In addition, it was understood that the patient was informed and her consent was obtained 24 hours before the surgical operation in accordance with the procedures and principles defined in the patient rights regulation. Under these conditions, the board of expertise decided that the undesirable situation following prominent ear surgery was a complication and was no fault of surgeon. The report prepared in this manner was submitted to the court. While this case report was being prepared, the judicial process was ongoing.

In conclusion, the main point evaluated in a malpractice claim against a physician is to determine whether the physician has behaved in accordance with the standard of care and patient rights together with the standards of care in his approach to the patient. This situation has been defined with sharper limits by the judicial authorities in Turkey, especially for plastic and reconstructive surgeons and dentists, as per the work contract in the Code of Obligations, "delivering the work flawlessly". In some countries, when there is a claim of medical malpractice, the decision is left to the discretion of the judge, while in Turkey, the judges make their decisions after taking the opinion of an expert panel consisting of competent medical experts.

In this case report, although the expert committee decided that the physician was not responsible for any compensation, the existence of a patient who suffered material and moral damage suggested that a system should be established to insure patients before such surgical operations. The establishment of such a system, which is valid only for that particular surgery, unlike general or supplementary health insurance, would reduce unfounded malpractice claims against physicians.

Conflict of interest

The authors declare that they have no conflict of interest.

Authors' Contribution Statement

To the design, writing, and analysis of this study, as well as medico-legal evaluation of this case, were all significantly and directly intellectually contributed to by all authors involved. All authors contributed to the preparation of the text, reviewing drafts, evaluating the content, and ultimately approving the version for publication. They have accepted that they are responsible for the accuracy of the case, and they have approved the sending of the article to Romanian Journal of Legal Medicine.

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