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Evaluation of the Biocompatibility and Effectiveness of the Nitinol Designed Implant on the Reshaping of the Rabbit Ear Cartilage

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Abstract

Introduction: Otoplasty is a relatively common surgery to reshape the ear deformity. In this study a new treatment for prominent ears using an implant made from nitinol(nickel-titanium alloy), forged into a predetermined shape was tested on rabbits to check the biocompatibility and effectiveness.

Materials and Methods: In this experimental study, designed nitinol implants (size: 0.15 × 0.2 × 0.15 mm) were applied and inserted in medial part of rabbit ear in anterior or posterior surface, the data were collected and analyzed after 2 months. We evaluated prosthesis durability and tissue response of samples to nitinol by examining their pathology.

Results: Of total 18 prostheses, 6 (75%) of the prostheses implanted in the posterior surface of the rabbits' ears remained intact and 40% of the prostheses implanted in the anterior surface of the rabbits' ears were extruded. Statistical analysis did not show a statistically significant relationship between the placement of the prosthesis and its final result (P=0.5) but the result was better in posterior according to extrusion.

Conclusion: In general, it can be said that the nitinol-designed implants have high tissue compatibility and can be an effective method in the treatment of prominent ear, if the insertion technique and location is well selected and this prosthesis is good option for other part of head and neck.

Keywords: Prominent ear; Prosthesis; Anti-helix; Nitinol; Otolplasty

Introduction

Prominent ear is the most common congenital ear deformity that affects 5 percent of the world's population [1,2]. Prominent ears have been defined as an ear projection or helix-mastoid distance of 2 cm or more [3]. The main problem in almost 70% of cases is an anti-helix disorder that leads to PE.

This deformity has profound psychological and social effects on patients [4], particularly in countries with certain cultural and religious beliefs like Iran. Therefore, therapeutic interventions aimed at correcting the anti-helix shape in most cases improves the quality of life of patients with prominent ears [4,5].

A wide variety of otoplasty techniques for restoring acceptable, normal and symmetric appearance of the ears have been described [6]. Designed techniques can be placed in two general categories; cartilage-cutting and cartilage-sparing (suturing) techniques [7]. Recent trends in otoplasty techniques have been moving toward less invasive options, ranging from nonsurgical newborn ear molding to cartilage-sparing surgical techniques and even incision less, office-based procedures [1]. The aim of cartilage-sparing procedures is to reshape the antihelix while limiting the risk of permanent damage to the cartilage [8]. Adopting an effective and safe technique should be based on proven efficacy and effectiveness [9].

One of the new minimally-invasive techniques for reshaping the antihelical fold while limiting the risk of permanent damage to the cartilage is earfold implant, made by Allergan plc, Dublin, Ireland, which is made of nitinol, a titanium-nickel alloy [8]. Kang et al. [10] noted that earfold implant is not a suture, although it reproduces many of the same effects, nor is it an external splint. Nevertheless, the implant is able to exert a corrective effect by reshaping the cartilage in a predictable and reproducible manner without the need to sculpt it. Additionally, earfold implants are quick to insert.

In this method, with the help of an implant, the possibility of tissue damage and atrophy and secondary problems is lower compared to previous methods. Additionally this topical and rapid treatment is more affordable. Therefore, it is much more beneficial, particularly in developing countries. However, it helps to develop different prosthesis for other part such as nose, larynx and palate.

Methods

The present study was an experimental study to construct and evaluate the adaptation and effect of a device on rabbits. Ethical approval to conduct the study was obtained from ethics committee of Iran university of medical sciences.

This study was carried out from January 2020 to March 2020 in the animal lab centerofIran university of medical sciences.

According to previous studies and ethical considerations, 5 rabbits were tested during this study.

Procedures

The aim of this experimental study was to perform the necessary experiments on the compatibility of nitinol metal. According to the studies that used this metal and confirmed its tissue compatibility, the prosthesis we used in the present study was made of nitinol [8,10-15]. The effectiveness of this type of prominent ear treatment on the rabbit

animal model during two phases in the animal laboratory of Iran university of medical sciences.

First phase

Subcutaneous implant design and implantation with the aim of forming the outer ear cartilage in the rabbit ear and producing prostheses.

After design approval, the mold was made to cut the nitinol sheet as desired. A nitinol sheet with a thickness of 0.7 mm was prepared and the desired shape was designed according to present samples, the metal was cut with a laser machine, and repeated attempts and errors were made so that we could get the desired angles accurately. Due to its crystalline structure, nitinol can return to the same shape as in the kiln at high temperatures, at 36°C. The samples were kept in a pre-designed mold for 5 minutes in a curved form in the kiln at 620°C. Then the gold was placed on the prostheses so that its color be similar to the skin color and not visible from under the skin (Figure 1).

Prosthesis had a size of 19 × 5.2 × 0.15 mm

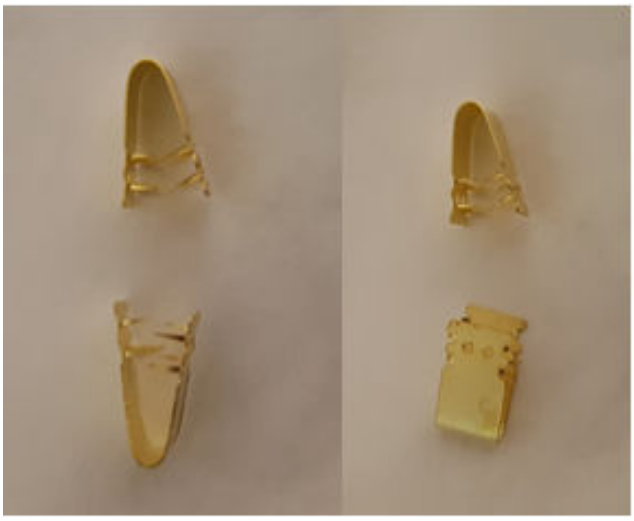

Figure 1: Prostheses shape.

Second phase

Animal experiments were performed on 5 rabbits in the animal laboratory with the aim of examining changes in the ear cartilages after 2 months.

Five white New Zealand albino male rabbits with an initial weight of about three kilograms (based on research, the decision was made to purchase adult rabbits because of the thicker cartilage).

All animals were anesthetized (by an animal veterinarian with ketamine) and with the help of insulin syringe, normal saline or lidocaine-was injected in hydro dissection and incision. The prosthesis was inserted at the insertion site and incision sutured with 5-0 nylon.

Before starting this study, a pilot study with limited number of prostheses was performed and we observed that lateral surface of rabbit cartilage because of its thin cartilage is not suitable place for prostheses, therefore medial side was considered for implantation.

So, all prostheses were placed between the proximal one-third and the distal two-thirds and also in medial site of the ear because the cartilage in this area was more stable and thicker. This placement was performed on the anterior or posterior surface of the animal's ear.

Anterior placement was done by incision of the skin in the anterior part and opening it in the subperichondrial plate by freer elevator, and then with the help of a hemostatic forceps, the prosthesis was installed so that the upper surface of the prosthesis towards the anterior and the lower surface be attached to the cartilage of the ear.

In posterior placement of the prosthesis, after incising the skin on the anterior surface of the ear, the cartilage was also cut and the prosthesis was placed behind the cartilage so that its bases were toward the cartilage and the upper part was toward the hairy skin.

Pathological examination of the samples was performed by sending adjacent tissue to the implant. The experiments assessed the tissue response to the implant and the tissue compatibility of the prosthesis in the animal phase.

Results

Day zero

18 prostheses were implanted, All were embedded in the medial surface of the ear at a proximal one-third distance and distal two-thirds.

10 prostheses were implanted in the anterior surface and 8 prostheses in the posterior surface.

2 months later

Of the 10 anterior prostheses, 6 prostheses remain intact and 4 prostheses were partially extruded when the extruded prosthesis was removed. According of next 8 posterior prostheses, 6 prostheses remain intact and 2 prostheses were partially extruded when the extruded prosthesis was removed (Table 1).

Then, biopsy were performed on the periphery of the extruded prosthesis, the pathology of which showed chronic inflammatory tissue and necrosis and granulation tissue without macrophage (pressure necrosis).

Biopsy were performed on the periphery of the healthy prosthesis implant, which showed fibrosis and cartilage tissue and healthy tissue without inflammation.

In this study, a total of 18 prostheses were implanted in the ears of 5 rabbits. 10 prostheses (55.5%) were placed in the anterior and 8 (44.4%) in the posterior surface. Finally, 12 prostheses (66%) stayed intact and 6 prostheses (34%) were extruded.

Insertion date	Visiting interval	Prosthesis number	Ear Surface		Extrusion Results	Pathological results	
			Ant	Post	Intact (not extruded)	Partially extruded	
First day	2 months	*	*		*		*1
		*		*	*		*1
		*	*			*	*2
		*		*		*	*2
		*	*		*		*1
		*	*		*		*1
		*	*		*		*1
		*	*		*		*1
		*	*			*	*2
		*		*	*		*1
		*		*	*		*1
		*		*	*		*1
		*	*		*		*1
		*	*			*	*2
		*	*			*	*2
		*		*	*		*1
		*		*	*		*1
		*		*		*	*2
Total		18	10	8	12	6	

Table 1: Prostheses information table and the result of their implantation in rabbit's ears. *1: Fibrous tissue, cartilage and healthy tissue and cartilage. *2: Chronic inflammation, tissue necrosis and granulation without macrophage (compression necrosis).

2 (25%) of the prostheses implanted in the posterior surface of the rabbit ears remained intact and 40% of the prostheses implanted in the anterior surface of the rabbit ears were extruded.

Statistical analysis did not show a statistically significant relationship between the placement of the prosthesis and its final result (P=0.5) (Table 2).

			Results		Total	P- value
			Intact	Extruded		
Prosthesis site's surface	Anterior	Number (%)	6(60%)	4(40%)	10(100%)	0.5
	Posterior	Number (%)	6(75%)	2(25%)	8(100%)	
Total		Number (%)	12(66.6%)	6(34.4%)	18(100%)	

Table 2: Final results of prostheses implantation based on prosthesis site's surface.

Discussion

Multiple studies have been performed to evaluate the physiological effects of nitinol; Kim et al., showed that nitinol stents have sufficient stability and tissue compatibility [16], similar to the results of our study on the histocompatibility of nitinol.

A study to investigate the effects of absorbable plates on rabbit ear cartilage showed that the implants placed on the anterior surface were extruded due to wound traction, but the implants placed on the posterior surface of the rabbit ears remained without inflammation and necrosis [17]. In another study by Serel et al., defects in the cartilage of rabbits ears were seen on the posterior surface of rabbits ears because the diameter of the cartilage in this area is larger [18]. Similarly, our study showed that posterior surface of the ear is more suitable for prosthesis implantation.

Therefore, this study suggests that the prosthesis is embedded in the posterior and medial surface of the ear using the anterior incision. The causes of this extrusion include the structure of the ear and cartilage and the difference in the thickness of the skin and cartilage of the rabbit ear on the medial and lateral surface. The rabbit cartilage is thicker on the proximal and medial sides and therefore can be a better place for prosthesis. Also, in the posterior surface of rabbit ears, the thickness of the skin is more than the anterior surface, which can be the reason for the better acceptance of prostheses in this area.

In order to investigate the tissue reaction to the prostheses, pathological examination of the samples was performed. Pathological examinations showed cartilage and fibrosis in cases where the prosthesis remained intact and acute on chronic inflammation, necrotic tissue, and macrophage-free granulation (pressure necrosis) were reported in cases where the prosthesis was extruded partially or totally. This can indicate a problem with the placement of the prosthesis and the reason for its extrusion.

Studies have been performed to evaluate the effect of this implant on humans. Kang et al. [10] conducted a study to evaluate the safety and behavior of *in vivo* implants in 39 patients.

The study found that 18 patients requested that their implants remain permanently in place. Side effects occurred in 8 patients, including extrusion, infection, and hypertrophic wounds. From the end of the study, up to 47 months, no new complications developed in any of the patients and patients were satisfied with the outcome of the treatment.

In Kang et al. study, 20.5% of patients developed side effects including infection and hypertrophic ulcers. In present study there were no signs of infection in rabbits. The only complication that occurred in the present study was implant extrusion which might be due to high tissue compatibility of the implant.

In another study, Kang et al. [8] examined the safety of earfolds implanted in the ears of 403 patients. This study also showed that side effects requiring intervention occurred in 39 of 403 patients (9.7%). These included implant repositioning (n=17 (4.2%), often due to visible prosthesis), skin erosion on the implant (n=15 (3.7%)), and infection (n=7 (1.7%)). There were no recurrences, hematomas, deformities, or intolerable scars in the patients in this study. The results of this study were similar to our findings.

In general, it can be said that the nitinol implant can be a new and effective method in the treatment of PE if the best place for implant placement is selected and the implant used has high tissue compatibility. Also, the placement of this prosthesis should be in such way that the least possible pressure is applied and it should be in the right depth and position with a suitable cartilage and skin cover to prevent its extrusion. This study showed that this prosthesis, has histocompatibility on the rabbit sample and may have a significant impact on the treatment of PE patients.

Conclusion

Nitinol implantcan be a new and effective methodin the treatment of PE if the best place for implant placement is selected. This Implant used has high tissue compatibility and it is less invasive method and has not major complication.

Choosing right place for placement of this prosthesis is important and affects results. Therefore it should be in the right depth and position with a suitable cartilage and skin cover to prevent its extrusion.

Suggestion

It is suggested that studies be performed to evaluate this prosthesis in human samples in a limited number to confirm the tissue compatibility and to evaluate the best place to implant the prosthesis and to evaluate the satisfaction of the patients. Also, other types of prosthesis could be designed for correcting deformities and problem in nose, larynx or palate.

Declarations

Authors' contributions

Availability of data and materials

The data presented is original and obtained in the animal laboratory of Iran university of medical sciences. It can be made available if required.

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Conflicts of Interest

There are no conflicts of interest.

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