NITINOL PISTON VERSUS CONVENTIONAL TEFLON PISTON: A SITUATION ANALYSIS FOR DATA MANAGEMENT

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ABSTRACT

Objective: *To compare the performance of the Nitinol piston with the conventional Teflon piston.*

Methods: *Conducted from the perspective of a retrospective study, this investigation focused on patients in public healthcare firms in a Vietnamese context. Particularly, the study examined the participants' medical records. The inclusion criterion was set in such a way that the participants were expected to have had pathologically and surgically confirmed otosclerosis diagnosis. From the perspective of the exclusion criterion, medical records of patients who might have been lost to follow-up, those who had insufficient audiometric data, and those who exhibited revision surgery were not considered for analysis. Also, this investigation focused on prosthesis lengths that stretched from 4.00 millimeters to 4.50 millimeters. Also, the diameter of the target prostheses was expected to range from 0.40 millimeters to 0.60 millimeters.*

Results: *Findings from the conventional Teflon piston group revealed 26.1900 ± 6.7600dBHL while the outcomes for the case of the Nitinol piston participants stood at 26.7900 ± 8.3300dBHL. The postoperative ABG average was also investigated for both groups. Regarding the Nitinol group, findings depicted values of 7.9200 ± 6.7500dBHL. At P = 0.018, results for the preoperative stage for this group stood at 26.7900 ± 8.3300dBHL. As such, it was concluded that the Nitinol piston group's preoperative ABG average was significantly larger than the postoperative ABG average.*

Conclusion: In summary, this study's results revealed that the success of stapes surgery depends on the accuracy of the prosthesis loop's crimping. From a data management perspective, the comparison of the performance of the conventional Teflon piston with that of the Nitinol piston suggests distinct advantages with the use of the Nitinol shape-memory prosthesis. Hence, the Nitinol piston forms a more effective, safer, and easier treatment option that could be applied to clinical or medical interventions such as those involving otosclerosis surgeries.

Keywords: *Nitinol, Piston, Teflon, Management.*

INTRODUCTION

In the recent past, many studies have examined the subject of stapes surgery. Particularly, most of these studies reveal that when prosthesis is attached firmly and adequately (onto the incus' long process), there is likely to be surgical success (Brar, Passey & Agarwal, 2012). In response to these growing scholarly investigations and insights, a Nitinol-based prosthesis, which is characterized by a self-crimping nature, has evolved (Brown & Gantz, 2007). For the majority of the postoperative outcomes, findings suggest that Nitinol pistons exhibit superior results. However, some studies contend that the Nitinol piston's superior nature (compared to prostheses that are marked by conventional manual-crimping) forms an inconclusive debate (Gerlinger, Toth, Bako, Nemeth & Pytel, 2008). According to Hornung, Brase, Bozzato, Zenk, Schick and Iro (2010), the inference regarding the superior nature of the Nitinol piston forms a controversial conclusion. In this study, the central aim was to provide a comparative analysis of the Nitinol piston versus the conventional Teflon piston. The main objective was to predict the efficacy of employing the selected prostheses in data management procedures, upon which inferences would be made relative to the nature of the performance of the selected prostheses.

LITERATURE REVIEW

Since the initial discovery of stapedectomy, significant advancements have been made. According to Huber, Ma, Felix and Linder (2003), the motivation behind these advancements has been to ensure that surgical outcomes are improved, with stapes surgery on focus. However, Knox and Reitan (2005) stated that prostheses and surgical techniques that have been developed recently reflect a great revolution but manual crimping processes poses crucial challenges to the process of stapes surgery, proving to be an uncertain step. Relative to the subject of surgical limitations, Lee, Wang, Lirng, Liao, Yu and Shiao (2009) observed that the challenges stretch beyond individual anatomic variations such as ear canal size and incus deformity pose challenges in relation to the manipulation and positioning of prostheses. Also, Machado and Savi (2003) cautioned that surgical limitations arise relative to the issue of inaccurate crimping in situations such as those involving asymmetrical, under-, or over-crimping. As avowed by Pudel and Briggs (2008), these surgical limitations imply that there is likely to be an improper prosthesis attachment, especially onto the incus. Raj, Gupta and Mittal (2017) observed further that the tertiary effect is that there are likely to arise problems such as surgical complications and failure. In the affirmation by Sorom, Driscoll, Beatty and Lundy (2007), it was highlighted that the latter problem tends to be compounded by the presence of less- experienced surgeons; aspects that imply that the need for further scholarly investigations regarding the selected prostheses could not be overstated.

For the majority of the previous scholarly investigations that have focused on the practice of stapes surgery, findings suggest that constant hearing restoration and effective sound energy transmission tend to be achieved through adequate and firm attachment of pistons onto the incus' long process (Rajan, Diaz, Blackman, Eikelboom, Atlas & Shelton, 2007). For about five decades, additional studies avow that there has been growing scholarly interest in the most effective, safe, and easy methods through which prostheses could be crimped to the incus. According to Spear and Crawford (2011), this scholarly interest has led to significant innovations, especially regarding the design of the prostheses. Whereas one of the most recently developed prostheses is the case of Nitinol piston prosthesis, some studies have highlighted the earlier versions of the prostheses (Sorom, Driscoll, Beatty and Lundy, 2007). According to Brar, Passey and Agarwal (2012), examples of the initial versions of the prostheses include the titanium-gold clip prosthesis, the Shepherd's crook prosthesis, and the Teflon memory effect prosthesis.

In the study by Brown and Gantz (2007), it was affirmed that the Nickel Titanium Naval Ordinance Laboratory (Nitinol) prosthesis entails reflects an alloy of nickel and titanium. Particularly, Gerlinger, Toth, Bako, Nemeth and Pytel (2008) stated that Nitinol constitutes about 50 percent titanium and 50 percent nickel
– in terms of the weight of the materials that constitute the alloy. Also, Hornung, Brase, Bozzato, Zenk, Schick and Iro (2010) stated that Nitinol exhibits a shape memory effect, with the findings by Huber, Ma, Felix and Linder (2003) stating that the role of this shape memory effect entails the provision of room for the alloy to change in shape – relative to an initial shape that the prosthesis might have memorized (upon heating). Among memory alloys, a study by Knox and Reitan (2005) highlighted further that Nitinol forms one of the most

commonly employed shape memory alloys. As contended by Lee, Wang, Lirng, Liao, Yu and Shiao (2009), features that account for the wide application of Nitinol include excellent elasticity and biocompatibility.

Specific and perceivably extensive biomedical applications with which this shape memory alloy (Nitinol) has been associated have also been documented. For instance, studies by Machado and Savi (2003) and Pudel and Briggs (2008) highlighted that Nitinol has continually gained application in medical or clinical processes such as those involving catheters, orthopedic implants, and orthodontic wires. It is also worth noting that recently, a new version of the piston prosthesis has been developed. This version constitutes a self-crimping feature and also exhibits a Nitinol wire loop and a fluoroplastic shaft (Raj, Gupta and Mittal, 2017). Notably, the Nitinol piston's shape memory effect provides room for the prosthesis to fashion itself precisely, uniformly, and securely, especially around the incus. As documented by Rajan, Diaz, Blackman, Eikelboom, Atlas and Shelton (2007), this nature of the Nitinol piston allows it to offer improvements in surgical results, with several studies concurring with this observation (Spear and Crawford, 2011).

According to Tenney, Arriaga, Chen and Arriaga (2008), the self-crimping nature of the Nitinol piston arises from the assertion that its wire loop can fasten itself around the incus' long process automatically, especially after a heat source such as laser forceps or bipolar is applied. The fastening occurs when the heat applied attains a temperature of 45°C. From these scholarly affirmations, it is evident that the literature is significant because it increases the understanding the Nitinol piston's self-crimping nature yields reductions in over- or under0crimping risks, besides simplifying the crimping maneuver.

Therefore, the last few years have seen the Nitinol piston gain an increase in scholarly interest, especially among otologists. Some of the comparative studies that have been conducted have compared the post- and pre-operative hearing outcomes (Brar, Passey & Agarwal, 2012) . Despite this promising nature of scholarly investigations, it is worth indicating that the subject involving comparisons between surgical outcomes that are obtained by employing conventional prostheses and those that are obtained after employing the Nitinol piston is yet to receive in -depth analysis (Sorom, Driscoll, Beatty and Lundy, 2007). For the few investigations that have examined this subject, most of the findings suggest that when the two groups of prostheses are employed, the hearing results do not reveal any statistically significant difference (Brown & Gantz, 2007). In data management, a question that arises is how do the hearing results linked to the Nitinol piston compare with those of the conventional Teflon piston? As mentioned earlier, some studies document that the Nitinol piston is superior to the conventional Teflon piston (Hornung, Brase, Bozzato, Zenk, Schick and Iro, 2010) but many scholarly outcomes avow that this inference is controversial (Gerlinger, Toth, Bako, Nemeth & Pytel, 2008), suggesting that the debate regarding the hearing results obtained after employing the two groups of prostheses remains inconclusive (Huber, Ma, Felix and Linder, 2003).

In populations such as those in the Asian context and developing countries on other continents, conditions such as clinical otosclerosis are less prevalent compared to communities, racial, or ethnic groups (such as Caucasians) (Knox and Reitan, 2005). This trend, as documented by Lee, Wang, Lirng, Liao, Yu and Shiao (2009), accounts for the perceived nature of the limited experienced demonstrated by the majority of surgeons. As avowed by Machado and Savi (2003), one of the reasons explaining this limitation in the surgeons' limited experience involves the relative paucity of scholarly investigations targeting the subject of stapes prosthesis in patients hailing from geographical contexts such as Asian countries. The eventuality is that in populations such as those in the Asian context, comparisons of the hearing outcomes obtained by employing the Nitinol piston with those that are obtained after employing the conventional Teflon piston are yet to receive in -depth examination. To contribute to the previous literature (and address the latter gap), this study strives to compare the results associated with the Nitinol piston and those that are linked to the use of the conventional Teflon piston.

MATERIALS AND METHODS

Conducted from the perspective of a retrospective study, this investigation focused on patients in public healthcare firms in a Vietnamese context. Particularly, the study examined the participants' medical records. The inclusion criterion was set in such a way that the participants were expected to have had pathologically and surgically confirmed otosclerosis diagnosis. From the perspective of the exclusion criterion, medical records of patients who might have been lost to follow-up, those who had insufficient audiometric data, and those who exhibited revision surgery were not considered for analysis. Also, this investigation focused on prosthesis lengths that stretched from 4.00 millimeters to 4.50 millimeters. Also, the diameter of the target

prostheses was expected to range from 0.40 millimeters to 0.60 millimeters. Indeed, the aim of using a uniform range of the length and diameter of the prostheses was to assure outcome validity, having tested the results of each type of piston without compromising and complicating the investigation via a significant variation of the lengths and diameters of the pistons, as Pudel and Briggs (2008) cautioned that any significant variations in these parameters could compromise the validity of the results, hence biased inferences and conclusions.

The research was designed in such a way that each patient was presented with pure-one audiograms. These audiograms were presented postoperatively and preoperatively. Issues that were used to govern the data compilation process involved air-bone gap and pure-tone average at the post- and pre-operative stages. In turn, the information's mean thresholds were obtained, with specific values at which the thresholds were established being 5, 2, 1 and 0.5 kHZ. In situations, where 3 kHZ as the threshold was absent, estimations were done based on the average of 4 kHZ and 2 kHZ.

To determine the air-bone gap and the pure-tone average, bone conduction and air conduction thresholds were applied. Notably, these thresholds were expected to have been recorded on the same audiograms. The comparative parameter that was used to discern the nature of the results obtained for the case of the conventional Teflon piston and the Nitinol piston entailed postoperative ABGs, which were set at ABG<10 dB.

From the perspective of data analysis, the interval level of the information obtained was compared using nonparametric statistical approaches, especially through the Mann-Whitney U test. Some of the interval level data that was analyzed via the nonparametric statistical approach included changes in the participants' ABG, postoperative and preoperative ABGs, preoperative BC and AC, follow-up duration, and age. To ensure that the post- and preoperative ABGs' levels of significant difference were determined, this study employed paired t-test samples. In situations requiring the determination of patients who were likely to reveal postoperative ABG closure in ABG<10 dB, their percentages were compared by using Pearson's χ_2 test. Notably, the SPSS software package was used to perform the study's descriptive statistics in the entirety – as well as the achievement of statistical comparisons between the prostheses (and among the participants) . To determine results that could be deemed statistically significant (hence worth considering as raw data for the final analysis and inference-making processes), P was set at $P<0.05$.

RESULTS

From the perspective of the demographic characteristics of the patients, the ranges of ages of those who had been exposed to the conventional Teflon piston was 24.0-58.0 years while those who had been exposed to the Nitinol piston had their age ranges lie between 27.0 and 63.0 years. Regarding the means and standard deviations of the ages of these two categories of the participants, those who were linked to the conventional piston had their results stand at 45.5700 ± 9.7600 while those who were linked to the Nitinol piston had their mean and standard deviation stand at 42.8100 ± 12.5800. Imperatively, 91 ears had been selected initially for purposes of data collection and analysis. Out of these, two had lost follow-up, three exhibited inadequate audiometric data, and two had revision surgeries. As such, seven of these ears were excluded from the study, making 84 ears to be considered as potentially eligible for consideration in the study. Another factor that was considered involved the effect of the learning curve, which saw the number of eligible ears reduce to 37. Of these, those that had been exposed to the conventional Teflon piston stood at 21 while those that had been exposed to the Nitinol piston stood at 16. These values represented 56.76% and 43.24% respectively.

The means and standard deviations were also calculated whereby the values for the conventional piston group were 14.0200 ± 3.8100 and 12.7600 ± 1.3800 respectively. Another factor that was examined entailed the gender of the position of the ear, whether right or left. For the conventional piston group, those whose right ears were considered were thirteen while those whose left ears were eight. For the Nitinol piston groups, the numbers were eight for each group (left and right ears). For the conventional piston participants, 56.8700 ± 10.5500dBHL was the mean preoperative AC, with the findings for the Nitinol piston participants standing at 56.0100 ± 12.4400dBHL. Regarding the parameter of the mean preoperative BC, values for the conventional Teflon piston participants stood at 30.6800 ± 9.9500dBHL while the Nitinol piston participants had their values associated with the latter parameter stand at 29.2100 ± 11.1200dBHL.

An additional variable that was tested involved the mean preoperative ABG. Findings from the conventional Teflon piston group revealed 26.1900 ± 6.7600dBHL while the outcomes for the case of the Nitinol piston participants stood at 26.7900 ± 8.3300dBHL. Notably, factors that supported the ease of comparison of the results for both categories of the prostheses involved closeness in the participants attributes such as

preoperative ABG, preoperative hearing levels, the duration of follow -up, and the age of the selected groups. On these variables, the groups from the conventional Teflon piston and the Nitinol piston did not exhibit statistically significant differences.

The postoperative ABG average was also investigated for both groups. Regarding the Nitinol group, findings depicted values of 7.9200 ± 6.7500dBHL. At P = 0.018, results for the preoperative stage for this group stood at 26.7900 ± 8.3300dBHL. As such, it was concluded that the Nitinol piston group's preoperative ABG average was significantly larger than the postoperative ABG average. In relation to the conventional Teflon piston group, results concerning the postoperative ABG had the average stand at 13.0900 ± 6.9900dBHL. For this group, the preoperative ABG average had been established as 26.1900 ± 6.7600dBHL, implying that the preoperative ABG average, similar to the case of the Nitinol piston group, was significantly larger than the postoperative ABG average. It is also worth noting that when the mean decrease in the ABG factor was tested, the conventional Teflon piston group had its findings stand at 9.0400 ± 9.9800 dB while the Nitinol piston group had its outcomes stand at 14.5300 ± 11.1100. On the one hand, there was no statistically significant difference in ABG mean differences between the two groups. On the other hand, ABG mean improvement in the conventional Teflon piston group was less compared to the case of the Nitinol piston group. Relative to the 10 dB-ABG closure, superior results were obtained for the case of the Nitinol piston group compared to patients who had been exposed to the conventional Teflon piston. Specific results saw the ABG closure for the conventional piston group stand at 33.00% while the Nitinol piston group had the 10 dB-ABG closure results stand at 75.00%.

DISCUSSION

Following the development of the Teflon-based prosthesis, more prostheses have evolved. These trends reflect significant changes or transformations in micro-surgery procedures. The Nitinol piston forms one of the most recently developed prostheses. The motivation behind the development of this prosthesis has been to ensure that the process of manual crimping, documented as a limitation in stapes or micro-surgery procedures, is eliminated. Whereas most of the previous literature indicates that the Nitinol piston-led stapes surgery exhibits superior postoperative results in terms of better hearing, the debate of whether this prosthesis could prove viable and replace conventional pistons such as the Teflon piston remains inconclusive.

It is also worth indicating that most of the previous scholarly investigations have offered comparative analyses of postoperative mean ABGs and demonstrated that the Nitinol piston is unlikely to have statistically significant advantages when compared to the case of conventional pistons, with the conventional Teflon piston unexceptional (Brar, Passey & Agarwal, 2012). However, some studies demonstrate an opposite conclusion that depicts the Nitinol piston as one that exhibits superior results (in terms of better hearing) than conventional pistons (Raj, Gupta and Mittal, 2017) . A question that arises is do the hearing results achieved via the use of the Nitinol piston differ from those that are achieved after employing the conventional Teflon piston? If so, which prosthesis exhibits superior hearing results?

In this study, both the conventional group and the Nitinol piston group exhibited significantly improved results at the postoperative stage – when compared to the nature of the parameters or variables that were tested at the preoperative stage. Imperative to note is that the postoperative hearing outcomes revealed through the application of the Nitinol piston proved superior to those that were reported via the use of the conventional Teflon piston, with consistency in the outcomes evident regardless of whether the test involved ABG closure or just ABG. Compared to some of the previous scholarly investigations that have focused on this subject, the current study's findings concurred (or proved consistent) with most of the results that the previous literature has documented. In stapes surgery, this concurrence was poised to contribute to the inconclusive debate and also aid in resolving the controversy that had been documented in relation to the affirmation(s) that the Nitinol piston forms a superior prosthesis compared to conventional pistons.

Given that better outcomes were observed relative to the use of the Nitinol piston, this study made several inferences regarding some of the factors that could explain the trend. For example, the straight alligator forceps and the piston loop exhibit a two-point contact – in the case of manual crimping, which hinders the loop's circumferential firm attachment onto the incus' long process. On the other hand, the Nitinol piston, which is self-crimping, exhibits uniform crimping onto the incus' long process; leaving no or very minimal room for gaps. With the piston loop and the incus exhibiting seamless and stable connections (when the Nitinol piston is applied), the eventuality is that the prosthesis' efficiency tends to be enhanced, ensuring that between the

ossicles and the piston, acoustical energy is transferred. Also, manual crimping is associated with the loss of sound transmission between the prosthesis and the incus, proving inferior to tight crimping, which exhibits reductions in the loss of sound transmission. Similarly, direct pressure and a notching effect on the long process of the incus results in wire loop loosening, eventually displacing the prosthesis; hence failure.

CONCLUSION

In summary, this study's results revealed that the success of stapes surgery depends on the accuracy of the prosthesis loop's crimping. From a data management perspective, the comparison of the performance of the conventional Teflon piston with that of the Nitinol piston suggests distinct advantages with the use of the Nitinol shape-memory prosthesis. Hence, the Nitinol piston forms a more effective, safer, and easier treatment option that could be applied to clinical or medical interventions such as those involving otosclerosis surgeries. This study's results indicated further that there is a dearth of literature concerning this subject in the Asian context due to the factor of limited surgeons' experience, a trend that accounts further for the lack of adequate scholarly investigations focusing on the subject of stapes prosthesis. As such, this study's outcomes are deemed insightful whereby they lay a foundation for future considerations of the efficacy of using the Nitinol piston versus the conventional Teflon piston in processes such as stapes surgeries. Overall, it is recommended that future studies examine trends in the use of the Nitinol piston in specific contexts such as Vietnam and Taiwan. Also, there is a need for future studies to investigate the relationship between the experience of surgeons and the effectiveness of using the Nitinol piston in stapes surgeries, upon which relevant interventions might be adopted and implemented – when the need arises; yielding improvements in health care service delivery in the target regions' local and national healthcare system.

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