

Review of Parameters Used To Assess Hearing Improvement in Tympanoplasty

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Abstract: Restoration of hearing is associated with resocialization of those affected and thus forms an important aspect of rehabilitation of individuals suffering from chronic suppurative otitis media. The surgeons with time have become more interested in returning back the hearing along with treating infection in the middle ear cleft. The zeal to restore hearing has led to the evolution of newer surgical techniques as well as improved indicators of surgical outcome. However, even after six decades of introduction of tympanoplasty, the goal of achieving stable and long term hearing results continues to be ambiguous. Different authors in the past have used different methods to compare the postoperative hearing results. Lack of universal criteria and the shortcomings of the different variables used in different populations has been a major obstacle in reporting of improved hearing results after tympanoplasty. Postoperative air conduction threshold, average hearing gain, post-operative air-bone gap and air bone gap closure are few of the parameters commonly used to assess the hearing outcome of tympanoplasty. The article provides a comprehensive review of the parameters when used alone or in combination with others and the results in terms of success obtained in light of these variables.

Keywords: Tympanoplasty, Air-bone gap, Hearing gain

I. Introduction

Tympanoplasty is the final step in the surgical conquest of conductive hearing loss and is the culmination of over 100 years of development of surgical procedures on the middle ear to improve hearing.^[1] The quest is still on to devise a way so as to give maximum postoperative hearing using minimal instrumentation. Although tympanoplasty has been widely discussed in the past, emphasis has always been on the surgical techniques and methods while the hearing results have more often been ignored or received very superficial treatment.^[2] Different methods have been used by different authors to report the pure tone audiometric postoperative hearing results in middle ear surgery in the literature.^[3] However there is no agreement amongst various authors regarding the standard criteria for reporting of hearing results. Not only do the criteria for success differ, but even those who use the same criteria use it in different ways.^[2]

The parameters most often used to report postoperative hearing results in major series are the mean hearing gain,^[4] postoperative hearing level^[5] and air-bone gap (ABG)^[6] or sometimes described as hearing gain exceeding 10 dB or 20 dB,^[4,7] as diminution of the air-bone gap within 10, 15, 20, or 30 dB^[8,9] attainment of social hearing (0-30 dB).^[4,10-13] The Committee on Conservation of the American Academy of Ophthalmology and Otolaryngology^[14] recommended stating the mean hearing gain in the range 500-2,000 Hz; a reduction of the air-bone gap to 10 dB and less, 20 dB and less, and 30 dB and less, as well as any deterioration of conductive hearing for reporting the hearing results. Elbrond^[15] calculated mean value audiogram for all frequencies whereas Tos^[3] used Threshold of intelligibility (TI) which included post-operative pure tone audiometry and speech audiometry. Similarly, the American Otosclerosis Study Group^[16] recommended that hearing improvement could be best estimated by observing the degree of closure of the air-bone gap, and the best way of assessing the improvement in a series of cases is by the percentage closure of air-bone gap.

Post-Operative Air Conduction Level

The postoperative air conduction levels acquired by pure tone average is the most easily acquired parameter and is internationally accepted. This is traditionally done by taking the average of air conduction (AC) levels at three speech frequencies i.e. 500, 1000 and 2000 Hz. The American Academy of Otolaryngology – Head and Neck Surgery guidelines,^[17] however, recommend inclusion of 3 KHz for measurement of hearing results. The final results may be reported in terms of average postoperative hearing levels, mean hearing gain which may exceed 10 or 20 dB or attainment of social hearing (0-30 dB). This seems to be a rational approach as the criteria are straightforward and easily understood by everyone. There is a clear explanation of method and the calculations involved so as to help make an accurate comparison. This is, however, an oversimplification as

the final results do not take into account the bone conduction and, thus, the air-bone gap which is the correctable part of hearing loss.

Livingstone *et al.*,^[18] reviewed the results of 138 tympanoplasty operations with regard to hearing improvement and cessation of otorrhoea. Hearing improvement results were evaluated under three headings:-

1. 0-30 decibel postoperative loss, *i.e.*, socially adequate hearing.
2. Improvement in hearing, but not up to the 30 decibel level.
3. No change

The hearing improvement achieved in Types I, II and III groups was encouraging in that nearly 60 per cent, of these cases acquired socially adequate hearing. Only 20 per cent of Type IV cases were in this category.

In the same year, Wullstein *et al.*,^[18] who gave an account of the theoretical and practical aspects of audiology of various types of tympanoplasties, reported the results in terms of post-operative air conduction levels. According to the authors, the results of tympanoplasties of type I-III with reconstruction of sound pressure transformation were good as long as the conductive loss was below 15 dB for the frequencies of 500-2000 Hz. For types IV-V only sound protection is present, hence, all results could be considered good where conductive loss was less than 30 dB.

Kolo *et al.*,^[19] in their study assessed the hearing results in terms of postoperative hearing threshold and hearing gain. The effects of some variables on hearing in 26 adult patients with CSOM after primary tympanoplasty were also reported. The overall mean pre-operative pure tone average was 49.58 dB (SD 18.608), while the overall mean post-operative pure tone average was 37.38 dB (SD 17.837); with the difference between the two (hearing gain) being 12.192 dB (SD 12.924). This was found to be statistically significant ($p < 0.05$). The authors concluded the primary tympanoplasty to be effective in improving hearing results in adults with CSOM even in those with advanced ossicular lesions.

Similarly, Shetty^[20] carried out a prospective observational study in 50 cases of CSOM and assessed the hearing improvement of various types and techniques of tympanoplasty. Out of these, 45 cases were tubotympanic type, and 5 cases were attico-antral. There was a gain of 18.8 dB in type I, 26.46 dB in type II and 20.27 dB gain type III tympanoplasty which was statistically significant. The mean preoperative hearing loss was 42.50 dB, and the mean postoperative hearing was 20.41 dB. The author thus concluded that tympanoplasty was a beneficial procedure for hearing improvement and the eradication of the disease.

Postoperative Bone Conduction Levels

Similar to the use of air conduction, the bone conduction level has been considered for assessment of hearing results by some authors.^[24-26] The mean difference in the pre and postoperative bone conduction levels with consistent improvement in the postoperative bone conduction thresholds has seen bone conduction as a parameter of measurement of hearing gain, though, to a variable extent.

Brackmann^[21] presented an article on the use of PORPs (partial ossicular replacement prosthesis) and TORPs (total ossicular replacement prosthesis) for reconstruction of the conductive mechanism. Rather than using preoperative air conduction as the standard, he used what he called a residual conductive deficit which compared the best of bone conduction levels (pre or postoperative levels) to the postoperative air conduction. By using the criteria for success to be air-bone gap less than 20 dB, 55% of the TORP cases and 73% of the PORP cases fell into the category.

Vijayendra and Parikh^[22] in their study of 500 patients evaluated changes in post-operative bone conduction in patients who underwent surgery for conductive or mixed hearing loss due to various reasons. The patients were divided in five equal groups each representing different causes for preoperative hearing loss who underwent appropriate surgical correction and had follow up audiogram available. There was a significant improvement in bone conduction in postoperative period in all the groups with maximum gain in otosclerosis and minimum in cholesteatoma. All other groups also showed a consistent preoperative bone conduction reduction with an equally consistent improvement in postoperative bone conduction to a varying degree. The author thus concluded that although the bone conduction thresholds were frequently elevated in chronic otitis media, tympanosclerosis and otosclerosis in pre-operative period, it might not be due to direct inner ear involvement in all the cases. In most of the cases it could be due to mechanical factors (so called Carhart effect or pseudoperceptive deafness). Successful results could be achieved in most of the patients regardless of the deteriorated bone conduction thresholds.

Lee *et al.*,^[23] in his study aimed to assess the elevation of bone conduction threshold in patients with chronic otitis media and to investigate the mechanism of this phenomenon. One hundred and six patients with unilateral chronic otitis media who had undergone a tympanomastoidectomy were reviewed retrospectively. The differences in the bone conduction thresholds between the diseased and normal sides were assessed and compared according to the duration of the disease and the presence of cholesteatoma. Postoperative changes in the bone conduction threshold were also assessed. The mean bone conduction thresholds were significantly elevated on the diseased side, ranging from 3.4 to 11.6 dB across frequencies, with a maximal elevation at 2000

Hz. The duration of disease and the presence of cholesteatoma did not affect the degree of the bone conduction elevation. After ossicular reconstruction, bone conduction thresholds improved significantly at all frequencies, with the greatest improvement being observed at 2000 Hz. These results suggested that the elevation in the bone conduction threshold in chronic otitis media is mainly caused by a change in the conductive mechanism in the middle ear.

Air-Bone Gap (ABG)

The ABG is calculated by taking differences between air conduction and bone conduction thresholds. Again this parameter has been used with considerable variability in different series. The hearing results have been reported in terms of postoperative air conduction and preoperative bone conduction, postoperative air and bone conduction, difference in postoperative ABG and preoperative ABG, diminution of air-bone within 10, 15, 20 or within 30 dB, reduction of the air-bone gap to 10 dB and less, 20 dB and less, and 30 dB and less.^[3] Many authors vaguely speak of the air-bone gap without setting out the parameters.^[2] In 1965, the American Academy of Otolaryngology in its report known as the Standard Classification for surgery of Chronic Ear Infections stated that preoperative air conduction and postoperative bone conduction at 500, 1000 and 2000 Hz should serve as the baseline for reporting hearing results.^[2] This variability in the definition of air bone gap reflected in the variable hearing results by various authors as discussed below.

Ojala and Sorri^[24] reported postoperative long term hearing results with special reference to the state and management of tympanic mucosa at operation in 627 ears. The improvement was also significantly better in dry ears than in ears which were moist at the time of operation ($p < 0.05$). The mean late deterioration in the air-bone gap after the first follow up year that was significant in all the groups of ears ($p < 0.05$) was used as criteria to report the hearing results. Similarly, the mean long term change in the air-bone gap from pre to late postoperative period showed an improvement of 3 dB in the ears with and a deterioration of 2 dB in the ears without ossicular reconstruction.

Air-bone gap was also used to evaluate the hearing results with prostheses in ossicular chain reconstruction procedures. *e.g.* Quaranta *et al.*,^[25] utilized costal cartilage prostheses in ossicular chain reconstruction procedures in 36 subjects operated on for a middle ear cholesteatoma with an intact canal wall tympanoplasty. In 18 patients PORP was used, while in 22 patients TORP was used. In the PORP group the mean preoperative air-bone gap (ABG) was 22.4 dB hearing level (HL); before the second stage the ABG was 37.9 dB HL, at 2 years it was 12.1 dB HL, at 5 years 15.3 dB HL and at 10 years 15.8 dB HL. In the TORP group the mean preoperative ABG was 31.6 dB HL; before the second stage the ABG was 41.1 dB HL, at 2 years it was 14.4 dB HL, at 5 years 17 dB HL and at 10 years 18.5 dB HL. In both groups the number of cases with a postoperative ABG of < 20 dB HL remained stable ($P > 0.05$) over time.

Similarly, Murphy^[26] carried out a retrospective study on 55 pediatric patients with chronic otitis media who underwent ossicular reconstruction with PORP and TORP from 1991 to 1998 and results were evaluated preoperatively and postoperatively for air-bone gap (ABG). Twenty-seven patients underwent ossicular reconstruction with TORPs. The average preoperative ABG was 40.1 dB, and the average postoperative ABG was 31.6 dB. Nineteen percent of children with TORPs had a postoperative ABG less than 20 dB, and 44% of children with TORPs had a postoperative ABG less than 30 dB. Twenty-eight patients underwent ossicular reconstruction with PORPs. The average preoperative ABG was 29.7 dB, and the average postoperative ABG was 22.5 dB. Forty-three percent of children with PORPs had an ABG of less than 20 dB postoperatively, and 71% of children with PORPs had a postoperative ABG less than or equal to 30 dB.

Mahadevaiah and Parikh^[27] reported their long-term experience in hearing and healing in 126 cases in terms of improvement in air-bone gap with special reference to the age (pediatric versus adults), ossicle status (presence or absence of stapes suprastructure) and type of cholesteatoma (Attic versus posterior-superior versus secondary acquired cholesteatoma). Modified ICW technique was performed in cases of cholesteatoma confined to the middle ear, attic and antrum with an intact sac. Serviceable hearing was achieved in 69% (87/126) cases over long term with an average improvement in post-operative AB Gap of 13 dB. The author thus concluded that modified ICW technique was a one-stage procedure (in majority of cases) with the lowest recidivism rate when compared to various other ICW techniques.

Shrestha *et al.*,^[28] studied the comparison of the preoperative and post operative hearing results in 41 patients undergoing canal wall down mastoidectomy with classical type III tympanoplasty using temporalis fascia. The pre and postoperative PTA was performed and evaluated. The postoperative hearing was assessed in terms of average ABG and size of ABG closure. Mean preoperative and postoperative air-bone gap were 37.8 dB and 29.8 dB with a net gain of 8 dB. The postoperative PTA-ABG ranged from 15-61.2 dB. Hearing results after type III tympanoplasty varied widely showing statistically significant improvement in mean postoperative PTA-ABG but there was a great variation. Therefore, the authors suggested that canal wall down mastoidectomy with type III tympanoplasty could be performed without fear of impairing hearing.

The reliability of cartilage in improvement of tympanoplasty results were assessed many a times comparing the preoperative and postoperative air bone gaps. Cavaliere *et al.*,^[29] reported personal experience with “tragal cartilage shield” tympanoplasty in 306 adult patients. The overall average preoperative pure-tone average air-bone gap was 43.79 ± 7.07 dB, whereas the postoperative (1 year after surgery) pure-tone average air-bone gap was 10.43 ± 5.25 dB ($p < 0.0001$). Statistically significant improvement was observed up to 5 years after surgery. This study reveals that tragal cartilage shield tympanoplasty was a reliable technique with satisfactory hearing results.

Similarly, Altuna *et al.*,^[30] reported his experience with island cartilage tympanoplasty in revision cases and assessed the anatomical and functional outcomes in 60 cases. Average postoperative pure-tone audiometry air-bone gap was 13 ± 7 dB compared with 21 ± 11 dB preoperatively ($p=0.004$). An overall postoperative air-bone gap of 20 dB or less was achieved in 46 of the 60 patients (76.7%). The author thus concluded that tympanoplasty with island cartilage grafting was a reliable procedure for revision cases with excellent anatomic results as well as significant improvement of hearing.

Bernal-Sprekelsen *et al.*,^[31] evaluated the long-term anatomic and functional results after partial and total autologous cartilage palisade type III tympanoplasties to assess the efficacy of cartilage palisades in preventing recurrent cholesteatoma. Postoperative speech reception thresholds, speech discrimination scores, and postoperative air-bone gap were compared with preoperative levels. The outcomes of canal wall up and canal wall down procedures were compared. Speech reception thresholds did not change significantly. Speech discrimination scores were stable or improved in all patients. Postoperative air-bone gap was less than 10 dB in 29.8% of patients and between 11 and 20 dB in 32.3%. It was concluded that the cartilage palisade technique is effective for the reconstruction of the tympanic membrane and also prevents new retractions and recurrences of cholesteatoma. The functional results show that autologous cartilage grafts are able to transmit sound.

Neto *et al.*,^[32] carried out plug cartilage tympanoplasty in 23 patients with tympanic membrane perforations. In the initial auditory evaluation, the authors observed a minimum air-bone gap of 5dB and maximum of 30dB in the group with 1-10 years of age (mean value of 16.3dB) and, in the final postoperative evaluation, a minimum difference of 0 dB and maximum of 15dB (mean value of 5dB). In the other group, the preoperative values varied between 5dB and 50dB (mean value of 26.6dB). In the postoperative there was a variation of 0 to 30dB (mean value of 12.4dB). In three patients there was no gap improvement with tympanoplasty, all of them belonged to the group of older patients.

Combination Of Various Parameters

Very often the use of a single parameter for the measurement of hearing post tympanoplasty have not led to satisfactory results. This has paved way for considering more than one parameter simultaneously to analyse the different aspects of hearing improvement. This has definitely led to an insight into the factors which were initially ignored but, at the same time, has added more complexity into the results and thus more confusion.

Tos *et al.*,^[3] analysed the results of tympanoplasties by the various methods and compared the merits and demerits of the methods in the various disease conditions. The results of tympanoplasty in 260 patients with dry ears were assessed by different methods. Social hearing was attained in 67 per cent of the cases, the air-bone gap closed to 0-15 dB in 63 per cent, hearing improved by more than 20 dB in 56 per cent, by more than 10 dB in 87 per cent, and a threshold of intelligibility, assessed by speech audiometry, of 30 dB or better was obtained in 71 per cent. The mean hearing improvement in the 500-2,000 cps range was 23-2 dB, post-operative hearing 28-3 dB, air-bone gap 14-6 dB.

In another study, Vartiainen *et al.*,^[33] reported the hearing results of 277 patients with chronic otitis media undergoing one stage tympanoplasty. The mean follow up period was 6.4 years. Ossiculoplasty was performed using autologous ossicles or cortical bone. Mean hearing gain was 10.8 dB. Closure of post-operative air bone gap to within 20 db was achieved in 51% of cases. The best results were obtained with ears with intact stapes, while cholesteatomatous ears showed poorer results than other chronic ears. The findings showed that autologous ossicles and cortical bone were suitable for ossicular reconstruction in chronic ears, especially when one stage surgery was preferred.

Nomura *et al.*,^[34] carried out a study on hearing results after tympanoplasty in elderly patients with middle ear cholesteatoma and compared the results in terms of postoperative hearing level, hearing gain, air-bone gap (ABG) and change in bone conduction hearing level at 4000 Hz. Postoperative hearing level and hearing gain were found to be better amongst patients aged 20-29 and 30-39 years than in the elderly group, whilst ABG did not differ between all age categories. Changes in bone conduction hearing level at 4000 Hz were not significantly different between the age groups, suggesting that operative stress, *i.e.* mechanical stress or ossicular manipulation stress, does not aggravate sensorineural hearing loss in the elderly. The authors thus concluded that surgeons should be encouraged to perform tympanoplasty aimed not only at eradicating the lesion itself but also at improving hearing acuity in the elderly.

Mostafa *et al.*,^[35] studied the functional results in ossiculoplasty with different titanium prosthesis in sixteen patients. The first group received the classical titanium prosthesis ($n = 8$), and the second group received the Vario® titanium prosthesis ($n = 8$). Audiological assessment at 12 months revealed a significant improvement ($p < 0.0001$) in air-bone gap (ABG), in each group separately, with an average improvement by 21 dB in the classical and 25 dB in the Vario® titanium groups. However, there was no significant difference in improvement of the ABG between both groups. Closure of the average postoperative air bone gap within 20 dB or less was considered a successful hearing result and this was achieved in 83% (10/12) of cases in the classical group, 75% (6/8) of cases in the Vario® group and in 80% (16/20) in both groups. It was concluded that ossiculoplasty using either the classic or Vario titanium prosthesis showed a significant improvement in hearing.

Dawes^[36] in his article reported the postoperative air-bone gap (ABG) presented in 10 dB bins, ABG closure and air conduction threshold gain as the commonly reported indicators of tympanoplasty outcome. This review of the early results of tympanoplasty examined whether classifying surgery as either for hearing gain or for hearing preservation influenced the reported results. Closure of the ABG to within 20 dB was achieved in 72-94% of cases, the average postoperative ABG was between 13.1 and 17.1 dB with the postoperative air conduction threshold being between 27.4 and 33.5 dB. These figures were similar for both hearing preservation and hearing gain procedures. However air conduction threshold gain was significantly greater for the 'hearing gain' group (17 dB versus 0 dB) and was reduced to 8 dB by combining the two groups. Overall, indicating whether surgery attempted hearing preservation or hearing gain did not significantly alter the parameters used for reporting tympanoplasty outcome.

Gupta and Kalsotra,^[37] in a recent article, reported hearing improvement in different types of tympanoplasties in 50 patients. 18 of the cases had cholesteatomatous CSOM, while 32 were noncholesteatomatous CSOM. The average preoperative AC in the study was found to be 46.6 dB ranging from 20 dB to 112.5 dB, while the average postoperative AC was found to be 39 dB with an average gain of 7.6 dB. The four frequency average preoperative and postoperative air-bone gap (ABG) were found to be 26.48 dB and 20.17 dB respectively, with the average gain of 6.3 dB. The average ABG closure within 0-30 dB was seen in 33 (82%) of the cases. Social hearing was achieved in 86% of the cases in type I, 46% in type II, and 40% in type III tympanoplasty. Thus it was concluded that tympanoplasty definitely resulted in hearing improvement which, although, varied with different types of tympanoplasties.

It was thus observed that all the methods were fairly dependent upon the composition and severity of the material, and in some disease conditions the results appeared in a fairly favourable light if assessed by one criterion and in an unfavourable light when assessed by another. Therefore, the authors suggested that the results should be assessed by several methods simultaneously, preferably by the social hearing method, air-bone gap method, and hearing gain method, stating also the condition prior to the operation.

Other Parameters

The traditional methods of hearing assessment were relevant in terms of audiometry in that they assess the technical success of the procedure and lessen the monoaural disability. However, they do not necessarily assess whether the patient has had an overall benefit in hearing status, determined by many factors such as type of surgery, subjective benefit and the status of non-operated ear.

Ravikumar *et al.*,^[38] added another dimension to the post-operative hearing benefits. In his study of 60 patients, he compared the two methods of predicting the hearing benefit following middle ear reconstructive surgery, namely Glasgow benefit plot and Belfast rule of thumb. Hearing status was assessed pre and postoperatively by pure tone audiometry and by self assessment by patient with a questionnaire. The accuracy of predictability of hearing benefit by the two methods was compared with patients own assessment. Predictive value by two methods as per subjective benefit showed no statistically significant difference between the two methods (93% and 83% respectively).

Frequency-Wise Hearing Gain

Another interesting aspect of the post-operative hearing results was the distribution of hearing thresholds at different frequency levels and the post operative changes in threshold at different frequencies. Frequency-specific results were recorded and these were investigated, considering various surgical factors, such as type of surgery, type of ossiculoplasty and pathological findings.

Maroto *et al.*,^[39] assessed the hearing improvement after myringoplasty in 119 cases. Pure tone audiometry was conducted before surgery and after it, with a minimal postoperative period of 6 months audiometry at frequencies of 250; 500; 1000; 2000; 4000, and 8000 Hz was recorded. The author obtained a hearing improvement at all frequencies, except at 8000 Hz, at which surgery noticeably worsened hearing. The author concluded that lower the frequency of hearing loss, higher was the hearing improvement with best results at 250 Hz.

Similarly, Choi *et al.*,^[40] analyzed frequency-specific hearing results after surgery for chronic ear diseases while considering pathological findings and various surgical factors. In their study, 559 patients who underwent surgical management of chronic otitis media were reviewed retrospectively. Using pure tone audiometry, air conduction (AC), bone conduction (BC) and air bone gap (ABG) change between pre and postoperative tests were calculated for the frequencies of 250, 500, 1000, 2000, 3000, 4000 (AC and BC) and 6000 Hz (AC). The authors observed that air conduction AC results in the intact canal wall mastoidectomy showed improvement at each frequency except 4000, 6000 Hz. AC results in the tympanoplasty showed improvement at each frequency except 6000 Hz. AC and ABG results in the open cavity mastoidectomy showed improvement only at the frequencies of 250, 500, 2000 Hz. AC and ABG improved at low and mid frequencies but not in high frequencies above 3000 Hz when ossicular reconstruction was conducted. AC and ABG results also improved at low and mid frequencies in the cholesteatoma and ABG results improved at all frequencies except 3000 Hz in the non-cholesteatoma. The author concluded that after chronic ear surgery, AC and ABG changes improved, primarily in the low and mid frequencies.

II. Conclusion

In general, the results of tympanoplasty in terms of success obtained show considerable variability when assessed by different methods. None of the above methods fulfils all the criteria and each method has its drawbacks. The favourable result when seen with one parameter is found to be less favourable when assessed by another. The postoperative hearing levels and the hearing gain reflect the effectiveness of the surgeon and the ossiculoplasty methods; while the social hearing method gives the patient's hearing ability. These methods are useful to compare the results only when the preoperative hearing level is not poor. The air-bone gap affords a good supplement to the hearing gain and social hearing method but when used as the sole criteria it is least useful. It largely depends on the preoperative bone conduction levels. Its reliability is questionable as the patient's own statements regarding bone conduction may vary from one examination to other especially when it is impaired. It is also more dependent on the adjustment of the audiogram and the patient's ability to cooperate. Therefore, it is insufficient to state the results in terms of one variable only. The best method is to consider all these parameters simultaneously so as to provide a satisfactory picture of the postoperative hearing condition of the individual.

Comparing the results of tympanoplasty postoperatively requires a sustained effort to take into account the preoperative hearing status of the patient and exclude the confounding factors outside the control of the surgeon. In any case, it is normal for some variability to exist in the results of this type of surgery in terms of materials used, the ability of the surgeons, surgical indication and patient characteristics according to geographic area. Conducting protocols based on scientific evidence would standardise the criteria in all respects and more reliable results would be obtained, with the real possibility of an objective comparison of different set-ups.

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