Role of ‘low cost Indian implants’ in our practice: our experience with 1,572 pedicle screws

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Abstract

Purpose As Indian spine surgeons, we have to choose between ‘foreign implants’ and ‘Indian implants’. An Indian four pedicle screw rod construct costs 330 US dollars (one-third that of a similar foreign construct). About 60% of patients cannot afford expensive foreign implants. There is little written data evaluating how these Indian implants fare. The purpose of our study was to evaluate implant failure rate with Indian implants and compare it to foreign implants.

Methods We analysed results of 1,572 titanium pedicle screws used in 239 patients with a minimum 1-year follow-up. Patients were divided into Indian and foreign implant groups. Radiological failures were classified as (1) surgery and disease failure, (2) bone failure and (3) implant failure. The null hypothesis was that there is no difference between implant failure rate for Indian and foreign implants.

Results A total of 128 (53.56%) of patients could not afford foreign implants. We used 679 foreign and 893 Indian pedicle screws. In foreign implant group, there was a single incident of implant failure (0.15%). In Indian implant group, there were five such incidents (0.56%).

Conclusions (1) Rate of failure for ‘low cost’ Indian implants is very low (approximately 1 implant complication for every 200 screws). (2) There is no statistically

significant difference in failure rates for Indian implants and foreign implants (P -value = 0.2438). We recommend that Indian implants are a safe and viable option to make spine surgery cost effective in the Indian scenario.

Keywords Indian implants · Implant failure · Screw breakage · Screw rod disconnection

Introduction

One important decision we need to make as spine surgeons is whether to use ‘expensive foreign implants’ or ‘low cost Indian implants’. There are many reasons why we would like to use foreign implants for all our cases. These include research and development, marketing, company support, quality control and instrumentation. In the absence of an effective regulatory body in India, there is lack of information about the source and type of titanium alloy, details of the manufacturing process and quality control by the ‘Indian’ implant manufacturers. But, in spite of all these factors, about 60% of our patients cannot afford foreign implants. This is because of the phenomenal cost difference. A simple four mono axial ‘Indian’ pedicle screw rod construct costs about 330 US dollars. Whereas a similar foreign implant construct costs about 1,000 US dollars. Thus, we use Indian implants in about 60% of our cases. In spite of their widespread use all over the country, there is little written data evaluating how these Indian implants fare. Probably, this is because of the taboo associated with this topic. Thus, we were compelled to undertake this study to answer the following questions:

1. What is rate of implant failure with Indian implants?
2. How do Indian implants compare to foreign implants?

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Materials and methods

We analysed clinical and radiological results of 1,572 titanium pedicle screws used in 239 patients from March 2005 to December 2009. Only patients with more than 12 months follow up were included in the study. The mean follow up was 31.4 months (12–68 months).

The distribution of pedicle screw use according to indication was degenerative disorders (454), infections (441), osteoporotic fractures (180), spondylolisthesis (140), tumours (104), deformities (98), trauma (98), implant failures (30) and Anderson's lesions (27). The distribution of pedicle screw use according to the level of instrumentation was thoracic (345), thoracolumbar (525), and lumbar (702).

Markets in the developing countries like India have a huge number of 'local producers'. The quality of these producers varies considerably. We use 'Indian manufactured implants' only from three reputed local "European Conformity [CE]" certified companies. For all cases, the choice between Indian and foreign implants was made by patients based on their affordability. Patients were divided into Indian and foreign implant groups. Demographic data and operative parameters were noted for all patients.

Implant details including number of screws and mode of use (load bearing or load sharing construct) were recorded for both groups. If the axial load bearing capacity of the ventral column was intrinsically intact or surgically reconstructed, the mode of use was classified as load-sharing construct [1]. If the axial load bearing capacity of the ventral column was not intact, the mode of use was classified as a load-bearing construct [1].

Note was made of specific implant related intra operative adverse events: fractures (pedicle, lamina, transverse process or vertebral body), screw cut out and screw back out. We did not account for screw misplacement and cerebrospinal fluid leak as these are mainly due to surgeons' error.

Patients were followed up and radiological failures (Figs. 1, 2, 3, 4) were classified as

1. surgery and disease failure (occurrence of pseudoarthrosis, failure to control infection or recurrence of tumour),
2. bone failure (screw loosening, screw back out, screw cut out or screw toggling),
3. implant failure (screw breakage, thread fracture, rod breakage or screw rod disconnection).

The null hypothesis for our statistical analysis was that there is no difference between the implant failure rate for Indian and foreign implants. We drew a 2×2 contingency table and applied the two-tailed Fisher's exact test to calculate the *P* value.

Any implant exit and functional outcome (in terms of return to work and other activities) [2] at last follow up was also recorded.

Results

There were 113 males and 126 females with a mean age of 49.82 (3–85) years. The mean operative time was 150.5 (75–500) min and blood loss of 514.18 (50 to 1900) ml. 128 (53.56%) of our patients could not afford foreign implants. Thus, we used Indian implants in these patients and foreign implants in the remaining 111 patients.

Overall, we used 679 foreign pedicle screws and 893 Indian pedicle screws. In the Indian implant group, there were 74 load sharing constructs and 54 load bearing constructs. In the foreign implant group, there were 91 load sharing and 20 bearing constructs. There were seven specific intra operative implant related adverse events (three screw cut out, two pedicle fractures, one screw pull out and one vertebral body fracture) in the Indian implant group and nine similar events (four screw cut out, two screw pull out, one pedicle fracture, one lamina fracture, one transverse process fracture) in the foreign implant group.

In the Indian implant group there were three instances of surgery failure or disease failure (two uncontrolled infections and one tumour recurrence), but the implants remained intact and in place. Similarly, in the foreign implant group there were five such instances where the implants remained intact in spite of surgery or disease failure (two pseudoarthrosis, two tumour recurrence and one uncontrolled infection).

There were five instances of bony failure in the form of screw back out (two tuberculosis spine fixation with severe osteoporosis, one case with uncontrolled infection, one osteoporotic fracture in a chronic heavy smoker, one osteoporotic fracture) in the Indian implant group and two similar instances (one osteoporotic fracture in a chronic heavy smoker, one degenerative scoliosis fixation with severe osteoporosis) in the foreign implant group.

The summary of the implant failures we encountered is shown in Tables 1 and 2.

In the foreign implant group (679 screws), there was only a single incident of implant failure (0.15%). This was a screw rod disconnection in a degenerative scoliosis fixation in a 57-year-old man who also had a bony failure. At last follow up, he had pain and proximal junctional kyphosis for which revision instrumentation was advised.

In the Indian implant group (893 screws), there were five instances of implant failure (0.56%). We recorded two asymptomatic screw breakages in a 58-year-old female with a L₄ thyroid metastasis, where a load-bearing construct of pedicle screws was used for stabilization.

Table 1 Implant failure rate in Indian and foreign implant groups

Group	Patients (no.)	Screws (no.)	Screw breakage	Thread fracture	Rod breakage	Screw rod disconnection
Foreign	111	679	0	0	0	1
Indian	128	893	3	0	0	2

Table 2 Details of implant failure cases

Patient no.	Age/sex	Indication for surgery	Level	Implants	Implant failure	Contributing factors	Symptoms	Resurgery
4	58/F	Metastasis	Lumbar	Indian	2 broken screws	Load bearing construct	Asymptomatic	–
53	63/F	Tuberculosis	Lumbar	Indian	1 broken screw	Load bearing construct	Asymptomatic	–
105	74/M	Tuberculosis	Lumbar	Indian	1 screw rod disconnection	Load bearing construct	Symptomatic	Revision pedicle screw instrumentation
107	74/M	Degenerative spondylolisthesis	Lumbar	Indian	1 screw rod disconnection	–	Asymptomatic	–
179	57/M	Degenerative scoliosis	Lumbar	Foreign	1 screw rod disconnection	–	Pain	Advised resurgery

Similarly, one asymptomatic screw breakage occurred in a 63-year-old female where a load-bearing construct of pedicle screws was used for stabilization for lumbar tuberculous spondylodiscitis. 1 asymptomatic screw rod disconnection was seen in a 74-year-old male who underwent transforaminal lumbar interbody fusion for degenerative spondylolisthesis. Another 74-year-old male, who underwent stabilization with a load-bearing construct of pedicle screws for lumbar tuberculous spondylodiscitis developed one screw rod disconnection in addition to bony failure and had to undergo second surgery with revision pedicle screw instrumentation.

There was no rod breakage or screw thread fracture in any of our patients. The *P* value on comparing the implant failure rates for Indian and foreign groups was 0.2438.

Implant exit was required in five cases. In the Indian implant group, one patient required implant exit for persistent infection whereas one young female got her implants removed by choice. In the foreign implant group, two patients required implant exit for persistent pain whereas 1 needed implant exit for prominence under the skin.

112 of 128 patients where Indian implants were used had good or excellent functional outcome (87.5%). In the foreign implant group, 97 out of 111 patients had good or excellent functional outcome (87.4%).

Discussion

More than 53% of our patients, coming to a premier private sector tertiary referral centre in India, cannot afford expensive foreign implants. The fact that we used 55.81%

(893) of the pedicle screws we studied (1,572) in these 53.56% patients (128) suggests that as the number of screws increases more and more patients opt for Indian implants.

The occurrence of specific intra operative implant related adverse events was more for the foreign implant group (9 events) as compared to the Indian implant group (7 events). We believe that these intra operative adverse events are mainly because of surgeons' error and implants or instruments have little role to play in their causation. Screw cut out, which was the most common adverse event for both groups, occurred mostly during attempts at tightening without the use of an anti torque device.

There were instances of surgery or disease failure in both the groups. These events act as a testimonial to the fact that no matter what implants are used, the outcome of the procedure depends upon the planning and skill of the surgeon. The ultimate goal of most spinal surgeries is fusion and eradication of disease or tumour. If these goals are not met, the surgery will fail even if foreign implants are used.

Similarly, there were instances of screw backing out resulting in surgical failure in both the groups. These have been rightly classified as bony failure and not implant failure. Osteoporosis is one factor which should always be accounted in the preoperative planning [3, 4]. As surgeons, we have the options of using sublaminar wires (unpublished data), hooks [5], or cement augmented screws [6, 7] in severely osteoporotic cases. In addition, the least we can do is to investigate these patients with bone densitometry and start them on anti osteoporotic treatment. It is the responsibility of the surgeon to identify these patients pre

Fig. 1 Screw rod disconnection in a patient where trans foraminal interbody fusion was done using Indian implants

Fig. 2 Screw rod disconnection and bony failure in a patient where degenerative scoliosis fixation was done using foreign implants

operatively and take appropriate measures to prevent bony failures. Failing this, surgical failures (like the ones shown in our study) are bound to occur, no matter what implants are used.

Overall, 4 (66.67%) out of 6 implant related complications (for both groups combined) remained asymptomatic and did not adversely affect the surgical outcome. Unlike arthroplasty, spinal implants do not need to last a lifetime [8]. Pedicle screw failure in itself is not necessarily associated with a bad result [9].

The rate of failure for Indian implants was 0.56% and that for foreign implants was 0.15%. The rate of pedicle

screw failure in world literature has been reported to be high, ranging from 2.6 to 4.9% [10–12]. In a study of low cost stainless steel pedicle screws used in India in 1980s, the rate of breakage was 9% [9]. But all these reports are more than a decade old. We believe that the quality of pedicle screws, manufactured globally as well as locally, has improved in recent times.

On comparing the observed failure rate for Indian implants with that of foreign implants, we obtained a *P* value of 0.2438 (>0.05). Thus, this observed difference in failure rate is statistically not significant. But in absolute terms, the failure rate of ‘Indian implants’ was five times

Fig. 3 Bony failure in a patient where Indian implants were used for osteoporotic fracture fixation

Fig. 4 Screw breakage in a patient with L4 metastasis where Indian implants were used as a load bearing construct

that of ‘foreign implants’. Though this can be seen as a trend, the rate of failure for Indian implants is still very low (approximately 1 implant complication for every 200 screws).

The events of screw breakage (3) were only seen in Indian implant group. This may be because of the fact that 54 load-bearing constructs were used in the Indian implant group as against only 20 in the foreign implant group.

Interestingly, all implant failures occurred in the lumbar spine. This may be accounted for by increased mobility and load bearing requirements of the lumbar spine.

The rate of implant exit in both groups was similar. There were two implant exits in the Indian implant group as compared to three implant exits in the foreign implant group. The functional outcome in both groups was also similar. In the Indian implant group, 87.5% had an excellent or good functional outcome, whereas in the foreign implant group, 87.4% had excellent or good functional outcome. Even in literature, the use of implants has not shown a positive correlation with the clinical outcome of the patient [13, 14]. A limitation of our study is that differences in design (screw diameter, rod diameter, etc.) were not taken into account when comparing ‘Indian’ and ‘foreign’ implants. Moreover, there are similar design differences amongst ‘Indian implants’ produced by different manufacturers. But, our study makes only one broad group of ‘Indian’ implants, without taking these manufacturing differences into account.

Furthermore, this is a pilot study with less number of cases. In future, we intend to undertake a prospective randomized control trial with higher number of cases to conclusively prove if there was actually no significant difference between ‘Indian’ and ‘foreign’ pedicle screws.

Another important factor that has not been addressed by our study is the quality of instrumentation of ‘Indian manufacturers’ that sometimes increases the ‘fiddle factor’. This is so, especially in challenging situations like deformity surgery. We feel that good instrumentation does increase the surgeon comfort. But, surgeon comfort also depends upon being familiar with the instrumentation. Over the years, we have developed our comfort in using locally manufactured instrumentation. At the same time, local manufacturing gives a chance of improvisation in the instrumentation system depending upon the surgeons’ requirements.

Our study shows that,

1. Rate of failure for ‘low cost’ Indian implants is very low (approximately 1 implant complication for every 200 screws).
2. There is no statistically significant difference in the failure rates for Indian implants as compared to foreign implants (P value = 0.2438).

The outcome of spine surgery is dependent on many factors. Appropriate surgical technique is much more important than the type of implant used [8]. In the light of these findings, we recommend that Indian implants are a safe and viable option that should be offered to patients to make spine surgery cost effective.

Conflict of interest None.

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