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Original Research

Evaluation of the clinical outcome – subjective chewing ability, Oral Health Related Quality of Life (OHRQOL) and marginal bone loss in patients with a Single Implant Retained Mandibular Overdentures (SIROD)

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ABSTRACT:
Edentulism is a chronic condition and is considered as a handicap according to WHO. The palliative therapy for edentulous patients is a set of removable complete dentures. Though it is an economical option for the elderly, the conventional denture has certain shortcomings of which the major problem is with the retention and stability of the mandibular prostheses which often result in inability to masticate food, decreased self-confidence, decreased quality of life, decreased social contact and satisfaction1. Residual ridge resorption is an inevitable consequence of tooth loss and denture wearing with no dominant causative factor having been found. A simple type of anchorage was attempted to achieve a minimum variant by using one single median implant to retain mandibular complete denture. A marked improvement was noted in the patient reported outcomes that showed significant increase in subjective chewing ability after insertion of single implant to retain a mandibular overdenture.
Keywords: Mandibular angle, Etiology.

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INTRODUCTION

Edentulism is a chronic condition and is considered as a handicap according to WHO. The palliative therapy for edentulous patients is a set of removable complete dentures. Though it is an economical option for the elderly, the conventional denture has certain shortcomings of which the major problem is with the retention and stability of the mandibular prostheses which often result in inability to masticate food, decreased self-confidence, decreased quality of life, decreased social contact and satisfaction[1]. Residual ridge resorption is an inevitable consequence of tooth loss and denture wearing with no dominant causative factor having been found. The patients often complain of loose mandibular dentures along with pain during mastication, loss of retention and stability of complete denture. There is loss of retention and stability which poses difficulty in chewing the food[2].

To overcome these problems the overdenture concept came into existence in the year of 1960s.Osseointegrated implants have been used to improve denture support, stability, and retention. Overdenture supported by implant is considered as a viable treatment option for edentulous patients[3].

Because of the potential drawbacks of conventional mandibular dentures, rehabilitation of the completely edentulous mandible using implants, either to retain or support restorations is a predictable long-term treatment modality. There are several long-term studies, which prove beyond doubt, that implant retained prosthesis improved the quality of life of an elderly individuals[4].

According to the International mutual consent in 2002, McGill statement on overdentures, held in Montreal, it was stated that mandibular overdentures retained by two implants in the inter-foraminal area

should be the first-choice standard of care for the edentulous patient[5]. However, because of the treatment costs of this "standard therapy", many patients cannot afford treatment with two implants or are not willing to accept necessary bone augmentation procedures. Therefore, in order to limit costs, time and effort, attempts were made to retain mandibular overdenture using only a single implant[6].

The concept of SIROD in an edentulous mandible was introduced by Cordioli in 1993 and the five-year results were published in 1997 with implant success rates of 100% [7]. There is a new concept emerging, which uses a single central mandibular implant to retain the mandibular denture. Various other clinical studies thereafter, showed the ability of a single implant placed in the mandibular midline, is satisfactory during an observation period of upto 5 years. In addition to the possible cost savings with a single implant overdenture, there are potential surgical advantages as well, as compared to Two Implant Retained Mandibular Overdentures (TISODS).

SIROD is relatively less costly, requires less expertise, take lesser time during surgery, has potentially lesser postsurgical complications, need fewer adjustments and offers optimum retention[8]. Many studies have shown that midline region for single implant placement has many advantages. Traditionally, the anterior mandible has been considered a safe, preferred site for implant placement for overdentures even with severe ridge resorption and the anticipation of a relatively less challenging surgical procedure. It was also stated that usually in the midline area of mandible, larger bone ridges and thicker cortical bone can be found[9]. In addition to the favourable bone architecture, their benefits also include simplicity, inherent stress breaking, automatic reseating after denture displacement and limited lateral forces on implant during denture movements[8]. This treatment protocol is simple, with reduced morbidity and cost effective. In the Indian scenario such treatment can make an impact on the entire treatment modalities followed.

The purpose of this in vivo study is to evaluate the clinical outcome of the single implant retained mandibular overdentures in relation to parameters such as subjective chewing ability, changes in oral health related quality of life and the marginal bone loss around the implant in the midline region using radiographic method.

MATERIALS AND METHODS

An in vivo study was conducted in the Department of Prosthodontics, Crown and Bridge and Oral Implantology, H. P. Government Dental College and Hospital, Shimla, Himachal Pradesh. A total of twenty-five subjects were evaluated based on the chief complaints requiring replacement of teeth. After meticulous clinical and radiographic examination, ten maxillary and mandibular completely edentulous individuals (06 males and 04 females) were enrolled in this clinical study. Pre-operatory radiographs were taken for evaluation of bone morphology and for further reference in the future.

Presurgical assessment

Before initiating the procedure, all patients received thorough explanations of the study protocol and were required to sign a written informed consent form prior to being enrolled in the proposed study. A detailed medical and dental history of each subject was obtained along with preoperative photographs and radiographs. Preliminary assessment of soft and hard tissue was done clinically and radiographically. The surgical area selected for dental implant placement was evaluated clinically for width and to assess for any deep undercuts. Complete oral prophylaxis along with prescription of 0.2% chlorhexidine gluconate mouth rinse, twice daily for a period of 15 days before dental implant placement was advised. All vital signs were checked and a complete hemogram was done to evaluate the fitness of the patient prior to implant placement. Patients were advised to get RT-PCR test done for COVID and appropriate covid protocol was followed according to IPS COVID PROTOCOL GUIDELINES[10]. After all the requisite investigations have been performed, implant placement was planned.

Presurgical preparation

The maxillary and mandibular completely edentulous patients were rehabilitated with maxillary and mandibular conventional complete denture following recommended treatment protocol. The study included the patients in which the primary concern is related to poor retention of mandibular denture, instability, denture sores, phonetic problems. After the patient got habituated with complete denture, ridge mapping was done to obtain the implant diameter to be used.

Surgical preparation

The patients were pre-medicated with antibiotics (Amoxicillin 2g) 1 hour prior to surgery and were asked to rinse the mouth with Chlorhexidine 0.2%. Local anaesthesia was administered using Lignocaine with adrenaline in the ratio of 1:100000 at the involved site. After adequate local anaesthesia was achieved, procedure to place dental implant was performed.

Surgical procedure

The surgical procedure was initiated with an intra-oral crestal incision and full thickness mucoperiosteal flaps were elevated both buccally and lingually to expose the bone. The surgical stent/mandibular denture is positioned in the mouth, and a punch is made through the guide slot on the crest of the bone using pilot drill. The implant site was penetrated with the help of a pilot drill which was used to create a bleeding point at site of initial osteotomy when the surgical stent was still in place. After marking the implant site by surgical stent, the surgical stent was

removed and pilot drill was used to complete depth, followed by subsequent drills of increasing diameter to create an osteotomy site of required dimensions for each patient. A paralleling pin was used during osteotomy preparation to assess the drilling orientation. Implant was placed equicrestal into this osteotomy site with the help of a torque wrench. Healing abutments (Gingival formers) / cover screw was then screwed to the implants immediately after implant placement to close the opened implant site. Once the healing abutments were placed the surgical site was thoroughly irrigated and flap was sutured using non- resorbable 3-0 Mer silk sutures to achieve water-tight closure. The patients were asked to discontinue the use of denture for 7 days. Patients were prescribed with antibiotics and analgesics for 1 week, post-operatively.

Medication and follow up

Patients were recalled after 24 hours for review and then after one week for assessment of
post-operative recovery. Post-operative instructions were given to the patients regarding diet, oral hygiene maintenance and medications were prescribed. After 7 days, sutures were removed and intaglio surface of denture was relieved in the implant area and the denture was given to patient. Denture bases were relieved in the implant area by grinding and relined with a soft acrylic temporary material to avoid pressure and overload.

In the second stage surgery i.e., after 3 months, the healing abutment was replaced and the implant was loaded with ball attachment (male component- patrix) and conventional mandibular denture was converted into single implant retained mandibular overdenture. Metal housing and o-ring (female component- matrix) were picked up in the denture.

CLINICAL PARAMETERS

After receiving Single Implant Supported Mandibular Over Denture,

The baseline data i.e., at the time of providing retention of the lower denture by the implant's ball attachment (3 months after implant placement)

Three months after providing retention of the denture by the ball attachment (six months after implant placement)

The assessment was done for the following three parameters:

1. The **subjective chewing ability** which was recorded as patients' perception of chewing ability of hard and soft foods (standardised categories) and it was assessed using a *Visual Analogue Scale* (VAS)[6] having a numbered scale of 0 to 10, with 0 corresponding to the least and 10 corresponding to the maximum chewing ability. The patients were asked to indicate their chewing ability of hard food (apples) and soft food (potatoes) by scoring between 0 to 10. Patients' experience was evaluated using this numbered scale at the time of implant loading with the ball attachment overdenture and three months after using the single implant retained mandibular overdenture.
2. The **Oral Health Related Quality of Life** (OHRQoL) was assessed by the means of the ***OHIP-EDENT*** (Oral Health Index Profile – Edentulous) questionnaire which is an OHIP-49's adapted version retaining the most significant questions from each original subscale. The OHIP-EDENT includes seven subscales as shown below: Functional limitation (three items), Physical pain (four items), Psychological discomfort (two items), Physical disability (three items), Psychological disability (two items), Social disability (three items) and Handicap (two items). The subjects responded by rating the frequency with which oral health–related problems had impacted their daily activities at two different time intervals i.e at baseline and at three months after implant connection.

The Likert scale ranges from (0: Never, 1: Hardly ever, 2: Occasionally, 3: Fairly often and 4: Very often). The OHIP-EDENT is scored between 0 and 76 for an individual, and the lower scores represents a better OHRQol [1,11].

3. For radiographic evaluation, the patient was then recalled for follow up and recording was made at baseline and 3 months after providing retention of the denture by the ball attachment for evaluation of **crestal bone changes** with help of radiographs.

The measurements were recorded at:

1. Immediate post-operative
2. Baseline i.e., at the time of providing retention of the lower denture by the implant's ball attachment (three months after implant placement)
3. 3 months after providing retention of the denture by the ball attachment (six months after implant placement)

The standardized periapical radiographs were obtained at these time intervals were digitized using Digimizer Image analysis. The known implant length was used to calibrate the images in the computer software. To measure radiologic changes in peri-implant bone level, a fixed reference point had to be selected. The shoulder of the implant was taken as the reference point in the study. The distance from the point to the crest of the bone where it contacted the implant on mesial and distal sides was measured. The first point was selected on the shoulder of the implant. The second point was measured on the crest of the bone where it contacted the bone. The distance between the points was displayed. On each recall the distance was measured and changes in crestal bone levels were analysed. The results obtained were subjected to statistical analysis.

Follow up
The patient will be recalled after 3 months and 6 months for follow up for subjective clinical parameters and radiographic evaluation for the crestal bone loss assessment.

RESULTS AND DISCUSSION
The basic data was collected from ten patients and evaluated on the basis of subjective chewing ability, oral health related quality of life by using OHIP-EDENT, crestal bone loss at two different time intervals and immediate post operative complications if any.
The **subjective chewing ability** was recorded as the patients' perception of chewing hard and soft foods by using a visual analog scale of 0-10 with zero corresponding to the least and 10 corressponding to the maximum chewing ability. The hard food sample taken as a standard category was apple and the soft food sample chosen was boiled potato[6]. Patients' experience was evaluated using this numbered scale at the time of implant connection with ball attachment (at baseline) and three months after using the single implant retained mandibular overdenture.
The mean values and P-value were calculated at two different time intervals after the implant connection.
The subjective values given by the patients' themselves which were based on his/ her ability to chew apple shows that there is an increase in efficiency to grind apple after three months of loading implant with the ball attachment. ***Figure 1*** illustrates graphically the mean value for subjective chewing ability of hard food (apple) obtained in group 1 was 5.2 whereas the mean in group 2 was 8.5. The p-value obtained was 0.0001 which proved that the chewing ability was significantly improved in the patients three months after the implant connection. ***Figure 2*** depicts the mean value for group 1 was 7.5 and for group 2 was 9.5 for subjective chewing ability of mashed potatoes. The p- value was 0.0001 which is significant i.e., there is improvement in the ability to chew mashed potatoes, three months after the implant connection.
Although, the VAS scores obtained from the patients at baseline show a broader variability for hard food than for soft food, the scores after implant connection indicate improvement in chewing ability of both hard and the soft food item.
The **marginal bone loss** was evaluated using standardized periapical radiographs which are particularly well suited and preferred for longitudinal assessment of implant bone loss. The crestal bone loss calculated from the shoulder to the first visible bone to implant contact in group-1 (at baseline) and group-2 (at three months) in both mesial and distal sides of ten patients***. Figure 3*** graphically depicts the mean crestal bone loss on mesial side in group 1 is -0.346 whereas the mean value in group 2 is -0.449. ***Figure 4*** depicts the mean crestal bone loss on distal side in group 1 is -0.368 whereas the mean value in group 2 is -0.493. The bone loss is distal side of the implant is slightly more than on the mesial side but it is significant on both the sides after three months of implant attachment.
The **Oral Health Related Quality of Life (OHRQoL)** was assessed by the means of OHIP-EDENT questionnaire which was given to the patient at two different time intervals. It includes seven subscales on which 19 questions are categorized[11]. The scores were obtained for all the seven subscales in two different time intervals. The scores were added for each of the subscales and a total was obtained to find the mean values of two groups. ***Figure 5*** depicts the compilation of mean values of seven subscales at two different time intervals. The OHIP-EDENT is scored between 0 and 76, and the lower scores representing a better OHRQoL. The OHIP-EDENT was selected to measure the OHQRoL in edentulous patients as it appears to be a reliable and valid instrument to measure oral health-related quality of life. Differences in the OHIP-EDENT scores obtained at baseline and three months after implant connection were significant ($p < 0.05$) for the OHIP subscales, no significant reduction in OHIP scores was found for handicap. All other OHIP subscales were significantly reduced (***figure 6***). Therefore, the OHIP-EDENT was able to measure the improvement in OHRQoL of the patients treated with single midline implants where there was significant decrease in the scores. This is also in accordance with study done by Harder et al (2011)[6] and various other studies which were done on two- implant retained mandibular overdentures.
Results obtained from this study clearly indicates that performance of mandibular denture improve drastically with single implant. As per the results, SIROD performs very well by increasing the subjective chewing ability and enhancing the overall quality of life of such patients. Moreover, it doesn't burden the patient much when compared to TISOD and lies in the financial scope of the patient. One of the drawbacks of this study included the fact that the intraoral radiography was used to evaluate the radiographic changes in peri implant bone loss, which is quite a sensitive method. Also, the limitations include small sample size and over short observation time to evaluate the parameters. Another limitation of this study is that it did not include clinical prognostic factors such as standardised classification system for complete edentulism for the identification of more complex and higher risk situations that would influence treatment outcomes and treatment decisions[12]. Therefore, careful inclusion criteria for the patients to be selected in this study was done to avoid any potential prosthetic and surgical complications[13].

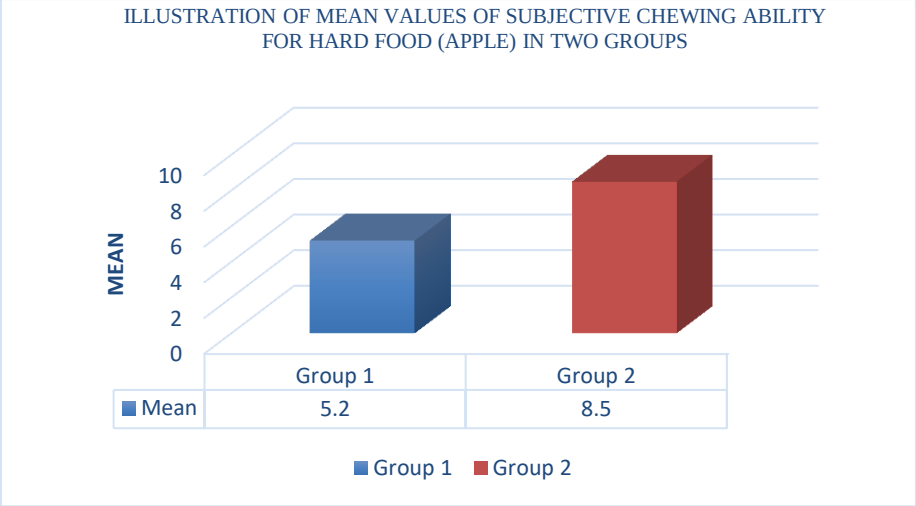

FIGURE 1

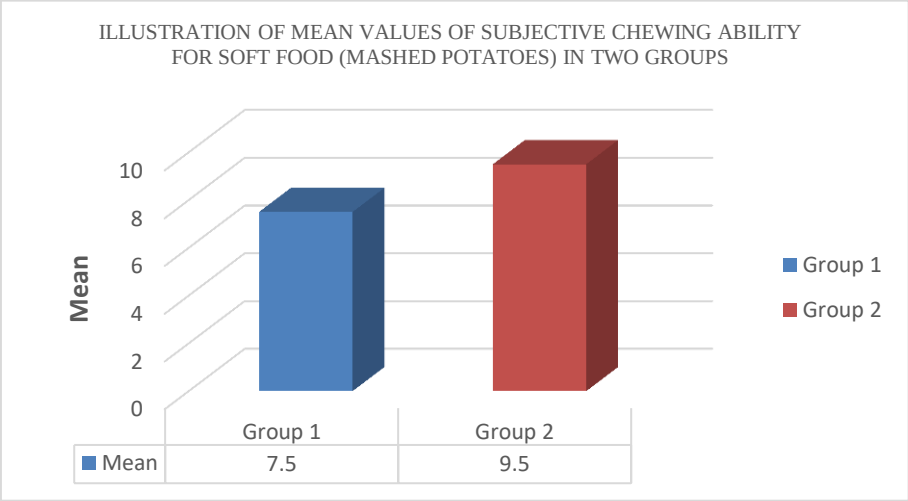

FIGURE 2

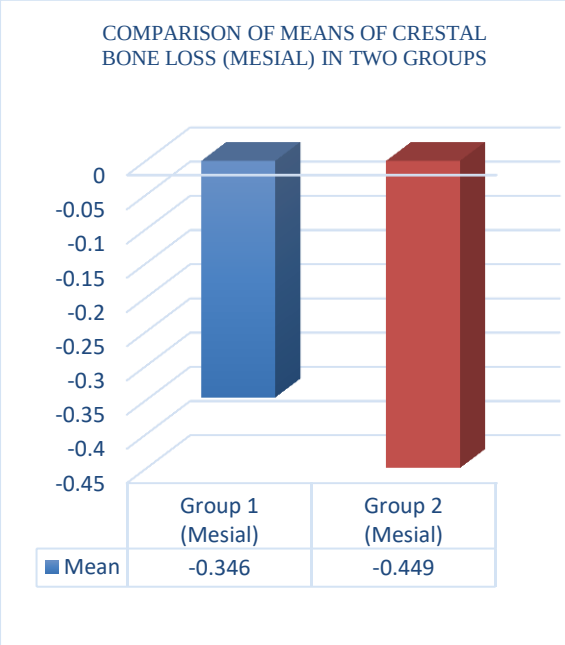

FIGURE 3

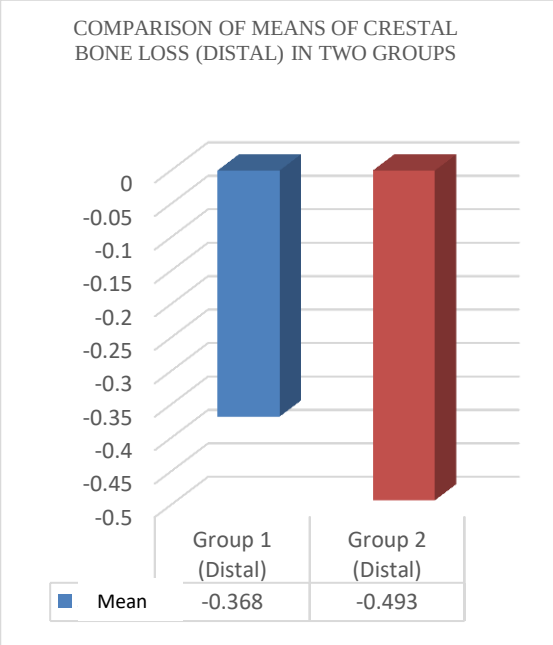

FIGURE 4

Subscales of OHIP-EDENT	GROUP 1 (BASELINE DATA)	GROUP 2 (AT THREE MONTHS)	P Value
	MEAN	MEAN	
FUNCTIONAL LIMITATION (FL)	7.7	3.4	0.0001
PHYSICAL PAIN (P1)	9.3	3.7	0.0001
PSYCHOLOGICAL DISCOMFORT (P2)	5.4	1.5	0.0001
PHYSICAL DISABILITY (D1)	8.4	4.6	0.0001
PSYCHOLOGICAL DISABILITY (D2)	3.8	1.2	0.0006
SOCIAL DISABILIY (D3)	4.2	1.6	0.0001
HANDICAP (H)	1.9	1	0.1296

FIGURE 5- ORAL HEALTH IMPACT PROFILE SUBSCALES AND TOTAL SCORES AT BASELINE (GROUP 1) AND AT THREE MONTHS (GROUP 2) (n=10)

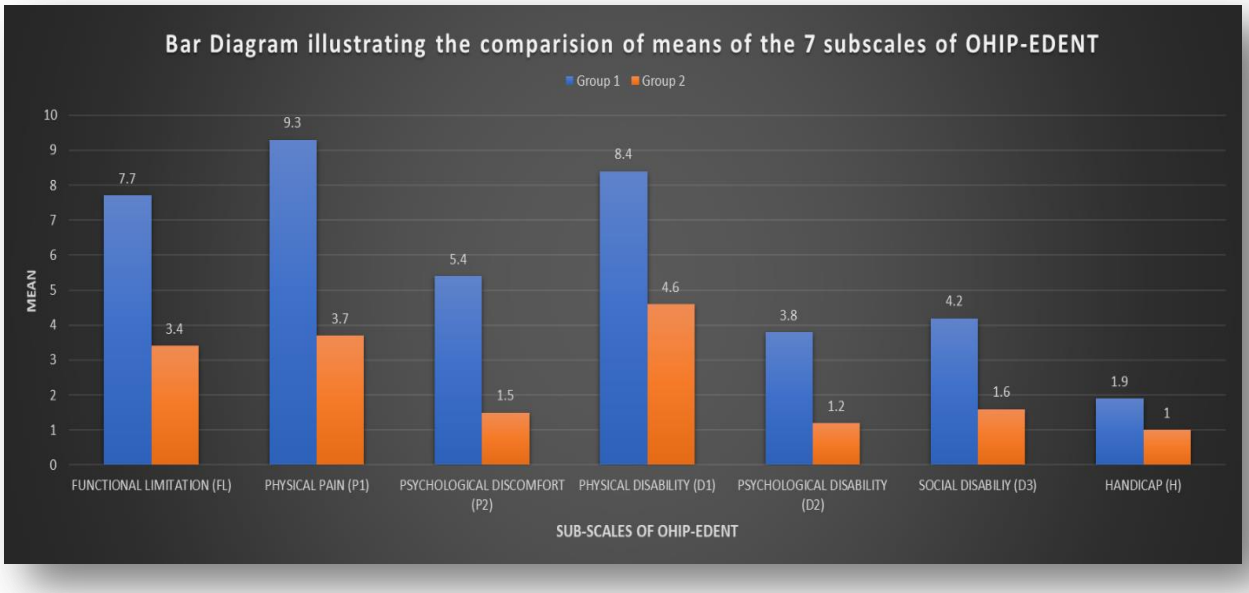

FIGURE 6 - Comparison of means of seven subscales of OHIP-EDENT in two groups

CONCLUSION

A simple type of anchorage was attempted to achieve a minimum variant by using one single median implant to retain mandibular complete denture. A marked improvement was noted in the patient reported outcomes that showed significant increase in subjective chewing ability after insertion of single implant to retain a mandibular overdenture. This corroborates the results from previous study done in the past by Harder et al[6]. A large improvement in OHRQoL scores were obtained in this study, similar to the studies done for a relatively longer time duration[6,14], confirming the findings obtained from this study. A low implant failure rate and low incidence of maintenance events were observed. However, this study like most of the previous studies, was conducted with a small sample size and over short duration. Therefore, there is a need for evidence derived from well- designed RCTs with larger sample size, longer follow-up periods and standardized surgical and prosthodontic protocols. Within the limitations of this study, it can be concluded that the SIROD improves subjective chewing ability in the

patients, hence provides better nutrition and enhances quality of life of the patients. The overall quality of life is significantly improved which suggested that it is a feasible alternative treatment plan for rehabilitation, with benefits to the patients in the long term.

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