IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 4 Ver. VII (April. 2017), PP 117-125
www.iosrjournals.org

To Study Mandakini off - Loading Device in the Management of Diabetic Plantar Ulcer

Dr.P.Ganesh Ms[1], Fmas, Fiages
Associate Professor Of Surgery
Govt Theni Medical College, Theni Tamilnadu India.

Dr.K.Kannan Ms[2],
Assistant Professor Of Surgery
Govt Theni Medical College, Theni, Tamilnadu, India.

I. Introduction

India has the largest number of people with diabetes in the world. Today the Indian diabetic population is about 61.3 millions which means that around 122 million feet are at risk of developing diabetic foot ulcer (DFU). It is expected that by 2025 this figure will reach nearly 73.5 million. Every 3 seconds a new case of diabetes is diagnosed and every 30 seconds a lower limb is amputated somewhere due to diabetes. Worldwide more than 1 million amputations are performed each year with up to 70% of these amputations related to diabetes. It is the commonest cause for admissions in people with diabetes . It is estimated that 15% of people with diabetes will develop a lower extremity ulcer during the course of their disease. Diabetic patients are 17 times more likely to develop gangrene of the foot than persons without diabetes and gangrene of the lower extremities occurs in 20- 30% of the patients with maturity onset diabetes.

DFU is basically a pathophysiological problem in biomechanics of the foot. Due to pan neuropathy in diabetes there is altered biomechanics and an insensate foot does not appreciate the pressure at plantar level and ultimately land up with a diabetic plantar ulcer. Offloading is the major solution to the plantar ulcer along with improvement of blood supply, control of infection and adequate wound care. The available offloading techniques are: bed rest, crutches, wheelchairs, zimmer frame, MCR shoes, ortho wedge shoes and total contact casting. All these procedures have many advantages and are efficient in wound healing, however, patient compliance and cost factor are the major disadvantages. The above-mentioned offloading devices are not widely used by the Indian rural population as they hinder their day to day activities. The rural population has to work daily to earn their livelihood and cannot afford to take bed rest for prolonged periods, use devices that bar them from doing their work or afford costly methods of offloading.

Objectives

1. To assess the efficacy of Mandakini offloading device in the treatment of Diabetic Foot Plantar Ulcer in terms of ideal off loading features, duration of healing of ulcer and recurrence of ulcer in rural population.
2. To compare Mandakini offloading device with conventional dressing in terms of duration of healing of ulcer, recurrence of ulcer and infection among the rural population.

II. Methodology

A prospective randomized comparative study, considering 110 patients with diabetic plantar ulcers admitted in the general surgery wards of govt theni Medical College Tamilnadu during the period of October 2016 to April 2017, satisfying the inclusion criteria mentioned below.

Inclusion criteria

All patients with DM with plantar ulcers

Exclusion criteria

1. Ulcers of Wagener's grade III, IV, and V
2. X-Ray showing osteomyelitis
3. Charcot's foot
4. Ischemic foot ABPI <0.4
5. Patients receiving corticosteroids, immunosuppressants, radiation

The selected patients underwent screening for a period of one to two weeks to stabilize the wound and institute appropriate medical and surgical lines of treatment like diabetic control, control of infection, wound debridement, correction of anemia and other medical illnesses. After the initial screening period the eligible patients were divided randomly into test and control groups.

Test group: The Mandakini offloading device was applied to the patients. Dressing was changed once a week and review was done weekly for 4 to 6 weeks.

Control group: The conventional dressing was applied and it was changed as and when required and review was done weekly for 4 to 6 weeks.

Reduction Of Wound Size And Area Measured In Sq Cm

The final parameters and wound characteristics of the two randomized groups were analyzed and compared.The selected patients were given educational materials called '20 steps towards foot health for people with diabetes' in their own language.Treatment of selected patients was done with bedside surgical debridement and a conventional topical antiseptic is applied when needed.

Statistical analysis used: Chi Square test and Fischer Exact Test.

Score For The Percentage Of Wound Covered By Slough

And Non Viable (Necrotic) Tissue

Score	Percentage Of Wound Covered By Slough And Non Viable Tissue
1	76-100%
2	51-75%
3	26-50%
4	11-25%
5	0-10%
6	No Necrotic Tissue

Score For Percentage Of Tissue Covered ByGranulation Tissue

SCORE	PERCENTAGE OF WOUND COVERED BY GRANULATION
1	No granulation tissue
2	<25%
3	25-74%
4	75-100%

III. Materials Used For Preparing Mandakini Off- Loading Device

1. Used pair of gloves
2. Dynaplast adhesive plaster
3. Method of preparation and application

1. Paired used gloves are rolled as we do for autoclaving
2. It is placed on adhesive surface of dynaplast and covered circumferentially with Dynaplast.
3. Edges of dynaplast are approximated by sharp pressure. Now the Mandakini Offloading device is ready to place.
4. It acts as a soft air cushion and offloads body weight.
5. Fore foot lesions are attended by applying the device proximal to the lesion.
6. Hind foot lesions are attended by applying the device distal to the lesion.
7. Number of gloves will be decided according to the weight of the patient.

Frequency of application

Every week The wound response was evaluated weekly using a VISUAL SCORE, both in case of Mandakini offloading device and conventional dressing.

Age Distribution:

Most of the patients fell within age group of 40 to 80 years. The mean +/- SD or the test group is (58.8+/-11.7) and control is (56.5+/-9.2) so age distribution is statistically similar between the two groups with (p=0.211)

Sex Distribution:

The male and female sex ratio is 58% and 42% in both the test and control groups. Hence the sex distribution is statistically similar between the two groups.

Size of the ulcers:

The mean size of the ulcer is 4.5 cm. The mean +/- SD of the ulcer in the test group (4.36 +/- 2.19) and in control group (4.36+/-2.18) is statistically similar between the two groups with (p=0.794).

Grade of the ulcers:

Most of the patients had grade I and II ulcers in both test and control groups. The grade of ulcer is

statistically similar between the two groups is (p=0.7).

Presence of necrotic tissue or slough:

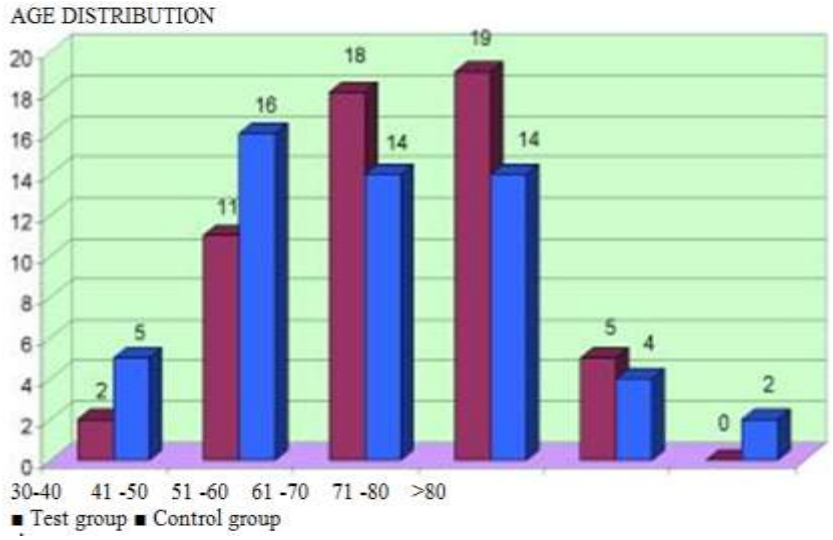
The number of patients with no necrotic tissue are significantly higher in test group at 3rd week follow up (p=0.277) at 4th week **(p<0.001)** at the 5th week **(p<0.001)** at 6th week **(p<0.001)** when compared to control group as per the chi square / Fischer exact test.

Presence of granulation tissue:

Number of patients with 75-100% wound filled are significantly higher in test group at 3rd week follow up (p=0.012) at 4th week (p=0.003) at 5th week (p=0.07) and 6th week **(p<0.001)** when compared to control group as per chi square / Fischer exact test.

Wound surface area:

Number of patients with no wound surface (NIL) are significantly higher in Test group at 3rd week follow up (P=0.025) at 4th week (P=0.015), at 5th week **(P<0.001)** and at 6th week **(P<0.001)** when compared to control group as per the Chi-square/ Fischer Exact test.



Size Distribution of ulcers

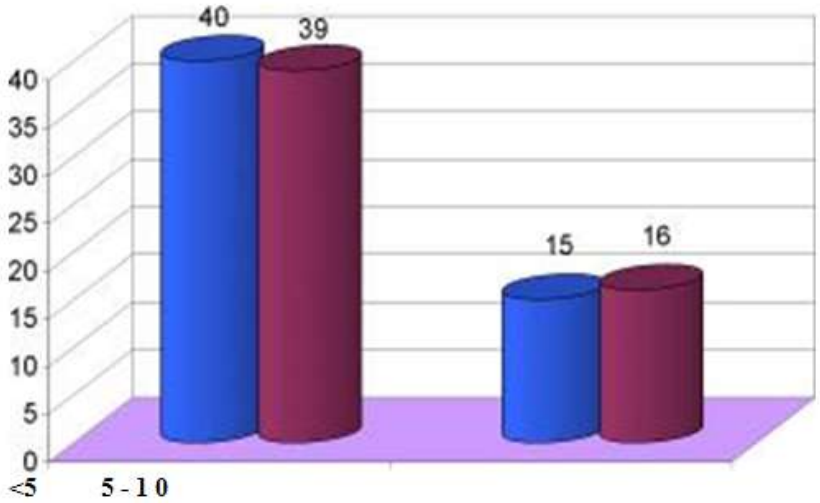
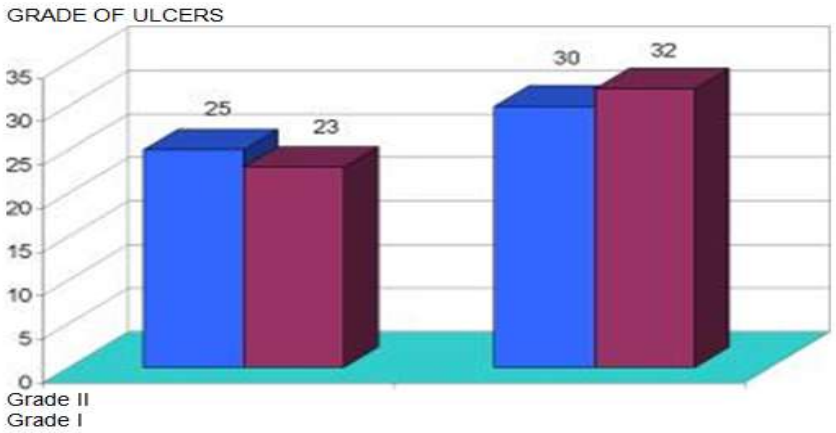
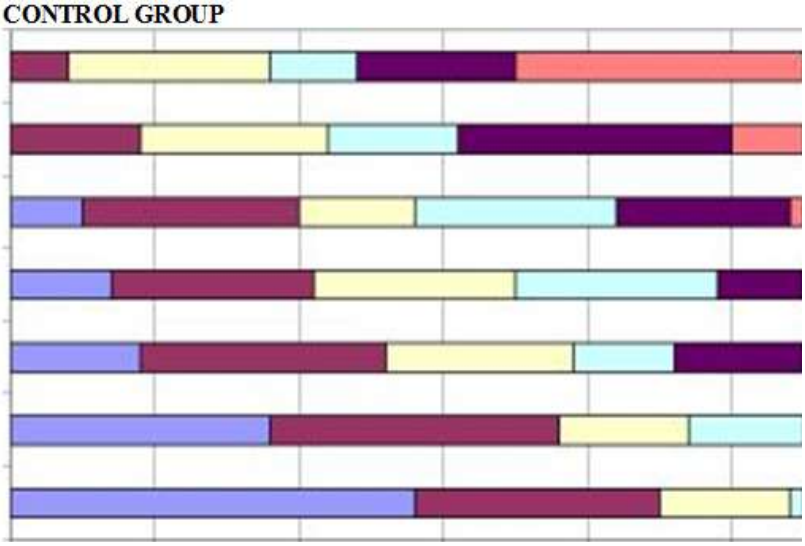


Table: 120 Size of the Ulcers in test group and control group



CONTROL GROUP



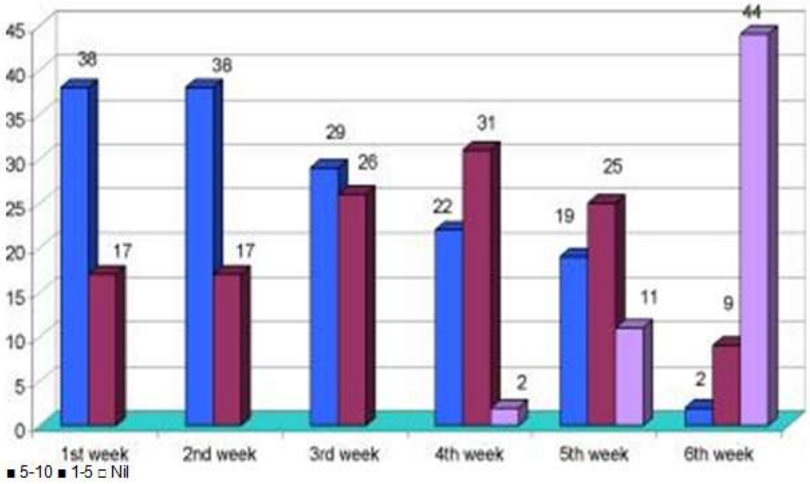
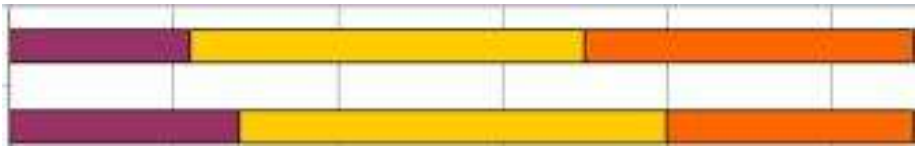
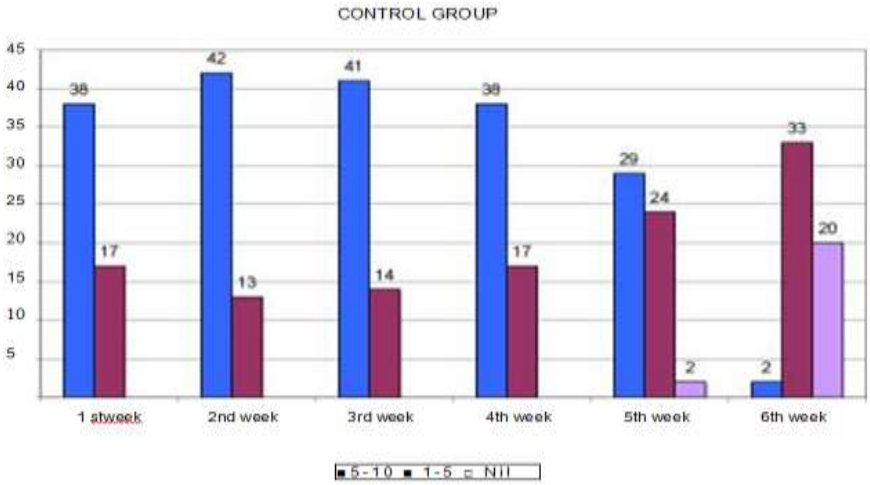


Table: 121 Wound surface area in test group and control group





IV. Discussion

The numbers of patients studied were 110 and were randomly divided into test group (55) and control group (55). Both the test and control groups were matched regarding their age, sex and grade of ulcer.

In addition, there was no significant difference between the two groups in regard to baseline ulcer size (P=0.794) and amount of non viable tissue/slough. The number of patients with no necrotic tissue were significantly higher in Test group at 3rd week of follow up (P=0.277) at 4th week **(P<0.001),** at 5th week **(P<0.001),** at 6th week **(P<0.001)** when compared to Control group. There was minimal loss of viable tissue in test group compared to control group because the number of bedside debridement required was less and was done superficially to remove the dead tissue only. The number of patients with 75-100% of wound filled by granulation tissue is significantly higher in test group at 3rd week follow up (P=0.012), at 4th week (P=0.003), at 5th week (P=0.077) and at 6th week **(P<0.001)** when compared to control group. The number of patients with no wound surface (NIL) is significantly higher in test group at 3rd week follow up (P=0.025), at 4th week (P=0.015), at 5th week **(P<0.001)** and at 6th week **(P<0.001)** when compared to control group. In test group, ulcer healed in 44 patients during follow up for 6 weeks. Among these 2 patients in 3 weeks, 8 patients in 4 weeks, 15 patients in 5 weeks and 30 patients in 6 weeks. In 11 patients, the ulcer did not heal completely but the size has

drastically reduced during the follow up period.

None of the patients in the test group had secondary infection. Conventional dressing was applied for 55 patients. Among these, ulcer healed in 20 patients during follow up period of 6 weeks. The ulcers of 2 patients healed in 4 weeks, 8 patients in 5 weeks and 12 patients in 6 weeks. In 30 patients, the size of the ulcer had reduced during the 6 week follow up but had not healed completely. The study demonstrated that offloading along with bedside debridement had cumulative effect in reduction of slough, increase of granulation tissue and faster wound bed preparation.The test group patients had increased growth of granulation tissue along with epithelialization which is generally co-related with the development of a granulating wound bed. All these were done with a visual score so it cannot be determined whether there was an increase in the granulation tissue as a result of the treatment or more granulation tissue was visible after debridement. The patients in the test group, however, produced better results. The ulcers also healed faster and had lesser recurrence rate due to offloading.

V. Conclusion

The study was done to give an insight to the depth of diabetic wound management as it has become the foremost problem in the recent times. Off loading is one of the comer stones of gold standard treatment in diabetic foot ulcer. The hospital wastes such as used gloves can help us to off load the body weight from ulcer site. The study shows the fine efficacy of Mandakini offloading device in terms of duration of healing of ulcer, no infection and no recurrence. It is an ideal offloading device for low socio economic rural population in developing countries. It reduces the duration of healing of ulcer when compared to conventional dressing. It completes the criteria to be called an ideal offloading device.

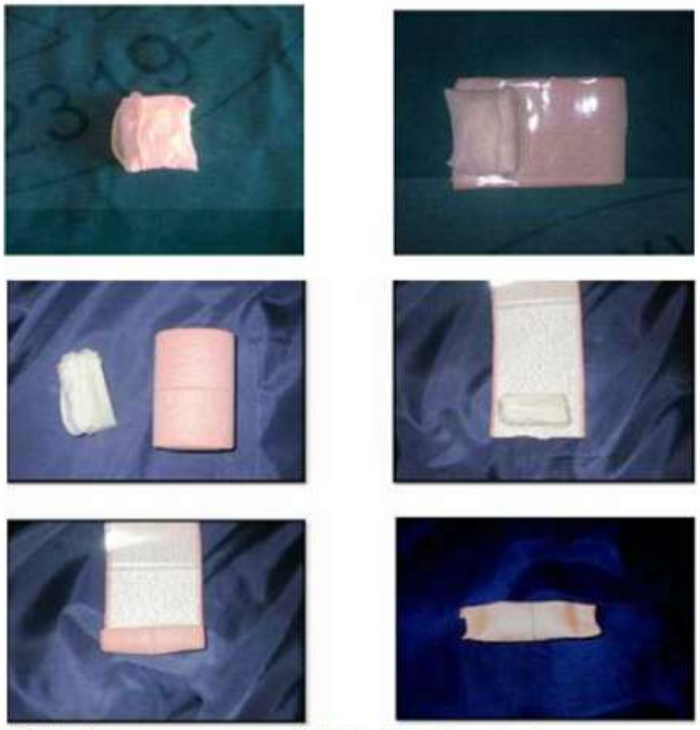
Summary

A concise introduction to diabetic foot ulcer, its incidence and complications is given with an account of the historical aspect of diabetes mellitus. These literatures in respect of clinico pathology, diagnostic aspect and the management of the diabetic foot ulcer are reviewed. The importance of off loading in the management of diabetic foot ulcer is discussed in brief Both the test and the control groups were matched regarding their age, sex and grade of the ulcer. In addition there were no significant differences between the two groups with respect to base line ulcer size. The reduction of slough is as early as 3rd week in the test group as the control group. The number of patients with 75-100% wound filled with granulation tissue is as early as 3rd week in test group as the control group where it took more than 4 weeks. The study concluded that Mandakini off loading device is an economical, effective and easy to apply offloading device in the management of diabetic foot ulcer in rural areas.

Bibliography

[1]. International diabetes federation. The global burden. Web:http://ww.idf.org/diabetes atlas/5 c/the-global-burden
[2]. King H, Aubert RE, Herman WH (1998) Global burden of diabetes, 1995-2025, prevalence, numerical estimates and projections. Diabetes care 21:1414-1431
[3]. International Diabetes Federation and International Working Group of the diabetic foot. Time to act. Netherlands, 2005.
[4]. Lipsky BA. A report from the International Consensus on diagnosing and treating the Diabetic Foot. Diabetes Metab Res Rev 20 (Suppl);68-77, 2004
[5]. Jeffcoate WJ, Harding KG. Diabetic Foot Ulcers. Lancet 361:1545-1551, 2003
[6]. Ramsey SD, Newton K, Blough D et al, Incidences, outcomes and cost of foot ulcers in patients with diabetes, Diabetes Care 22:3 82-3 87, 2000
[7]. Tenvall GR, Apelqvist J, Eneroth M, Costs of deep foot infections in patients with diabetes, Pharamcoeconomics, 18:225-238, 2000
[8]. Armstrong DG, Liswood PL, Todd WF (1995), Potential risks of accommodative padding of neuropathic ulcerations. Ostomy Wound management 41:44-49
[9]. Most RS, Sinnock P. The epidemiology of lower limb amputations in diabetic individuals, Diabetes Care 6:87-91, 1996
[10]. Trautner C, Haastner B, iani G, Berger M, Incidence of lower Limb amputations and diabetes, Diabetes Care 19:1006-1009, 1996
[11]. Reiber GE, The epidemiology of diabetic foot problems Diabet Med, 13:6-11, 1996
[12]. M. Venkataswamy Reddy (2002), Statistics for mental Health Care research, NIMHANS Publications India
[13]. Bernard Rosner, Fundamentals of Biostatistics, edition, Duxbuiy, 2000
[14]. Frykberg RG, Bailey LF, Matz A et al, Offloading properties of a rocker insole: Preliminary study, JAPMA 92:48-52, 2002.
[15]. Pinzur MS, Dart HC, Pedorthic management of diabetic foot, Foot Ankle Clin 6:205- 214, 2001
[16]. American Diabetes Association, Consensus development corporation on diabetic foot wound care, Diabetes Care 22:1354-1369, 1999
[17]. David R Sinacore, Michael J Muller (2008) Leving and O'Neil's The Diabetic Foot,.7 edition offloading for diabetic foot disease 13:287-304
[18]. Sharad Pendsey, introduction, In Diabetic Foot — A clinical atlas, 1 edition, New Delhi, J.P. Publishers, 2003, 3-4
[19]. Sunil V Kari, The economical way to offload diabetic foot ulcers (Mandakini Offloading Device) — Indian Journal of surgery 2010, 72 (2), 133-134
[20]. Harrington C, Zagari MJ, Corea J, A cost analysis of diabetic lower extremity ulcers, Diabet Care 23:1333-1338, 2002
[21]. Amato D PU, Lantin M, Basso K, Martens L, The cost of illness in patients with diabetic foot ulcers, Abstract, % Annul Meeting of American Diabetes Association, San Diego, 1999
[22]. Richard S Nell, The Foot, Clinical Anatomy for Medical Students, 5 edition, New York - Littile Brown Publishers 1995

[23]. Anne MR, Ming JL, Grant's Atlas of Anatomy, 10 edition, New York, Lippin Cott, Williams and Wikims 1999, 3 82-406
[24]. Peter LW, Roger W, Mary D, Lawrence HB, Gray's Anatomy, 37 edition, London, Churchill Livingston, 1992
[25]. Jeffcoate WJ, The incidence of amputation in diabetes, Actahir Beig 105:140- 144,2005
[26]. Laveri LA, Ashry HR, Van Houtm W, Pugh JA, Harkless LB, Basu S, Variations in the incidence and proportion of diabetes related amputations in minorities, Diabetes Care 19:48-52, 1996
[27]. Me Neely MJ, Boyko EJ, Ahroni JH, Stensel VL, Smith DG, Pecoraro RF, The independent contributions of diabetic neuropathy and vasculopathy in foot ulcerations, How great are the risk? Diabetes Care 18:216-219, 1995



Method to prepare mandakini offloading device

Plantar Ulcers Of Our Patients

Method Of Applying Mandakini Device